Permission to Take Part in a Human Research Study

Do not sign this consent if today's date is later than the stated expiration date above.

Title of Research Study: ***Attention-dependent neural oscillations in the human olfactory system, Study #STU00201349***

Investigator: ***Christina Zelano, PhD***

Supported By: This research is supported by Northwestern University and the National Institutes of Health.

Key Information:
The first few pages of this document include a summary of this study to help you decide whether or not to participate. Detailed information is provided after the summary.

Why am I being asked to take part in this research study?

We are asking you to take part in this research study because you are undergoing preoperative evaluation for epilepsy surgery and will need to have placement of invasive electrodes for seizure monitoring. Those electrodes happen to be on or near the brain regions encoding smell perception. This is research into the sense of smell and olfaction-related brain regions.

What should I know about a research study?

- Someone will explain this research study to you.
- Whether or not you take part is up to you.
- You can choose not to take part.
- You can agree to take part and later change your mind.
- Your decision will not be held against you.
- You can ask all the questions you want before you decide.

Why is this research being done?

The purpose of this research study is to investigate brain regions related to the sense of smell and nasal inhalation. The olfactory area of the brain directly connects to many other brain areas, including areas involved in breathing, emotion, memory, and learning. Very little is known about these brain regions and they are located in an area of the brain that is difficult to study. Taking part in this study may help scientists to better understand these brain areas, and may contribute to a better understanding of Sudden Unexpected Death in Epilepsy (SUDEP).

How long will the research last and what will I need to do?

We expect that you will be in this research study for around 3 to 6 hours, but that total time will be broken up into several shorter visits.

During pre-operative monitoring portion of the research, you will be asked to complete tasks ranging from 5 minutes to 1 hour, and will have breaks in between tasks. During the tasks you may be asked to smell and rate or identify odors; view and rate or identify images such as faces displaying different emotions, or other images on a computer screen; breathe through your nose or through your mouth, or other smelling, breathing, visual and learning tasks. During the electrical stimulation portion of the research, you may be asked to perform similar smelling, breathing, visual and learning tasks while electrodes in your brain are being stimulated.

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More detailed information about the study procedures can be found under the section **What happens if I say "Yes, I want to be in this research"?**

Is there any way being in this study could be bad for me?

The risks of having subdural electrodes implanted for pre-surgical evaluation will not be changed by your participation in this research experiment. Your participation in the electrical stimulation portion of the research will slightly add to the total duration of clinical electrical stimulation, and therefore may increase your risk of having a seizure. Note that experienced physicians and nurses are always present in the Epilepsy Monitoring Unit for rapid response and medication in the event of a seizure, as part of the standard clinical practice.

More detailed information about the risks of this study can be found under **"Is there any way being in this study could be bad for me? (Detailed Risks)"**

Will being in this study help me in any way?

There are no benefits to you from your taking part in this research. We cannot promise any benefits to others from your taking part in this research. However, possible benefits to others include a better understanding o***f the neural mechanisms behind e***pileptic pathologies such as Sudden Unexpected Death in Epilepsy (SUDEP).

What happens if I do not want to be in this research?

Participation in research is completely voluntary. You decide whether or not to participate. If you choose to not participate, there will be no penalty to you or loss of benefit to which you are entitled.

Your alternative to participating in this research study is to not participate.

Detailed Information:
The rest of this document includes detailed information about this study (in addition to the information listed above).

Whom can I talk to?

If you have questions, concerns, or complaints, or think the research has hurt you, talk to the research team: contact Greg Lane (Research Coordinator) at 312-503-7244 or Christina Zelano, (Principal Investigator) at 510-499-9363.

This research has been reviewed and approved by an Institutional Review Board (IRB). You may talk to them at (312) 503-9338 or irb@northwestern.edu if:

- Your questions, concerns, or complaints are not being answered by the research team.
- You cannot reach the research team.
- You want to talk to someone besides the research team.
- You have questions about your rights as a research participant.
- You want to get information or provide input about this research.

How many people will be studied?

We expect about 36 people here will be in this research study.

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What happens if I say "Yes, I want to be in this research"?

You will be asked to participate in this research study during your inpatient hospitalization in the Epilepsy Monitoring Unit at Northwestern Memorial Hospital, following the surgical placement of electrodes in the brain. Participation in this research study will not change the number or location of electrodes that will be positioned over or in the brain areas that are clinically necessary for your epilepsy surgical planning. This is no different from what would happen if you do not participate in this research study.

Your part in this research study will last around 3-6 hours, during your stay in the hospital. The stimulation portion will last around 30-45 minutes. The recording portion will last for around 3-5 hours and will be divided into several shorter sessions as you desire.

The experiment will take place after surgical placement of electrodes. On the day after electrode placement, and on each day for the duration of your clinically-determined pre-operative monitoring, you will be asked if you feel well enough to participate in the research study. If you do, we may ask you to perform smelling, breathing, visual, sound, and learning tasks. If you become fatigued or for any other reason, you can stop the experiments at any time.

The tasks may involve smelling various odors and rating their intensity, pleasantness and other parameters; looking at various images on a computer screen and rating their intensity, such as emotional expression on faces, and other parameters; breathing through your nose or mouth or holding your breath for short periods; listening to and rating sounds presented through headphones or computer speakers. We may also ask you to perform odor or visual or auditory naming or memory tasks. We may also measure your ability to detect odors and to tell them apart using standardized smell tests. The smell tests involve detecting odors and filling out a multiple-choice question booklet of odor identification.

These tasks will all take place in your hospital room. None of these tasks are intended to trigger your seizures, and none of the smells, images, sounds, breathing or learning tasks used in this research are known to cause seizures.

Before the tests begin, a pair of non-invasive electrodes may be placed on your skin (usually your fingers or hand) so that we can monitor your skin's electrical conductance, which changes in response to some external and internal physiological stimuli, such as emotions (internal) and sights, sounds, or odors (external). We will apply a small dab of isotonic gel on the electrodes, then tape or Velcro the electrodes on your skin. Neither the gel nor the electrodes are known to cause discomfort.

In addition, during the tests we will be monitoring your heart rate and respiration using the output from devices already in place for clinical purposes, following medical standard of care.

During your pre-operative stay, the epilepsy team will electrically stimulate the brain so they know which areas of the brain respond and should be spared in the event of surgery. This procedure is the medical standard-of-care and will take place even if you are not participating in the research study. After the epilepsy team has completed their stimulation tests, we will perform a few additional research tests looking for responses to the electrical stimulation in olfactory and olfactory-related areas of the brain. This research phase will slightly add to the total duration of electrical stimulation, and therefore may increase the risk of having a seizure.

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To deliver odors to you during the study, you may be asked to wear a comfortable mask or a pair of nasal cannulae (nose tubes) situated at the entrance to your nose, through which you will receive the smells. We will use the nasal mask or tubes both to deliver smells to you and also to monitor your breathing during the experiment. The mask will not interfere with your breathing in any way.

What happens if I say "Yes", but I change my mind later?

You can leave the research at any time; it will not be held against you.

If you decide to leave the research, contact the investigator so that the investigator can remove you from the research schedule.

Choosing not to be in this study or to stop being in this study will not result in any penalty to you or loss of benefit to which you are entitled. Specifically, your choice not to be in this study will not negatively affect your right to any present or future medical treatment.

Detailed Risks: Is there any way being in this study could be bad for me?

The risks of having subdural electrodes implanted for pre-surgical evaluation will not be changed by your participation in this research experiment. Note that experienced physicians and nurses are always present in the Epilepsy Monitoring Unit for rapid response and medication in the event of a seizure, as part of the standard clinical practice.

Your part in this research study may also involve the following risks:

(1) It is possible that you may have an allergic reaction to one of the odors. If you have any history of serious allergies, or a history of asthma, we may exclude you from the odor parts of this study. While none of the odors will be harmful to your health, some of them might smell unpleasant.
(2) Odors will be delivered to you either through a mask or through small tubes that will sit at the base of your nostrils. You may feel air blowing into your nose. We will adjust the mask or tubing to minimize discomfort resulting from the moving air.
(3) After the epilepsy team has completed their stimulation tests, we will perform a few additional research tests looking for responses to the electrical stimulation in olfactory and olfactory-related areas of the brain. This research phase will slightly add to the total duration of electrical stimulation, and therefore may increase your risk of having a seizure.

This study involves the use of your identifiable, personal information and there is a chance that a loss of confidentiality could occur. The researchers have procedures in place to lessen the possibility of this happening. See the section below titled: **"What happens to the information collected for the research?".**

Will it cost me anything to participate in this research study?

Taking part in this research study will not lead to any costs to you.

What happens to the information collected for the research?

Efforts will be made to limit the use and disclosure of your personal information, including research study and medical records, to people who have a need to review this information. We cannot promise complete secrecy. Organizations that may inspect and copy your information include the IRB and other representatives of this institution, and the National Institutes of Health. If we learn about current or ongoing child [or elder] abuse or neglect, we may be required or permitted by law or policy to report this information to authorities.

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To help us protect your privacy, we have obtained a Certificate of Confidentiality from the National Institutes of Health (NIH). The researchers can use this Certificate to legally refuse to disclose information that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings; for example, if there is a court subpoena. The researchers will use the Certificate to resist any demands for information that would identify you. You should understand that a Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If an insurer, medical care provider, or other person obtains your written consent to receive research information, then the researchers will not use the Certificate to withhold that information.

Data from this study will be retained for future use by the researchers. All data will be de-identified and stored on secure, password-protected servers at the Feinberg Medical School at Northwestern University. This data is accessible only to IRB-approved Study Team members, through secure on-campus connections or through secure Northwestern University VPN connections. This data will be stored until the end of the research study.

Data Sharing

De-identified data from this study may be shared with the research community at large to advance science and health. We will remove or code any personal information that could identify you before files are shared with other researchers to ensure that, by current scientific standards and known methods, no one will be able to identify you from the information we share. Despite these measures, we cannot guarantee anonymity of your personal data.

What else do I need to know?

If you become ill or are injured as a result of this study (medications, devices or procedures), you should seek medical treatment through your doctor or treatment center of choice. You should promptly tell the study doctor about any illness or injury.

The hospital [university, researchers] will not pay for medical care required because of a bad outcome resulting from your participation in this research study. This does not keep you from seeking to be paid back for care required because of a bad outcome.

If you agree to take part in this research study, we will pay you between $30 and $100 for your time and effort, an amount pro-rated for the percentage of the study you complete.

If you are paid by check, the Accounting Services at Northwestern University will be given your name, address, and Social Security Number in order to issue a check for your study participation. Study payments are considered taxable income and reportable to the IRS. A Form 1099 will be sent to you if your total payments are $600 or more in a calendar year.

HIPAA Authorization

We are committed to respect your privacy and to keep your personal information confidential. When choosing to take part in this study, you are giving us the permission to use your personal health information that includes health information in your medical records and information that can identify you. For example, personal health information may include your name, address, phone number or social security number. Your health information we may collect and use for this research includes:

- All information in a medical record
- Results of physical examinations

- Medical history
- Lab tests, or certain health information indicating or relating to a particular condition as well diaries and questionnaires
- Records about study medication or drugs
- Records about study devices
- Billing information

During this study, you may be coming to a Northwestern Memorial Healthcare Corporation entity (for example, Northwestern Memorial Hospital, Prentice Women's Hospital) for research appointments or to get clinical services, such as lab tests, needed for the study. When that happens, you will be scheduled for these services through the NMHC computer system. When a clinical exam or lab is done by NMHC or one of its employees for the purpose of this research study, that information will be kept in both NMHC's clinical records and in the study records.

The following clinical providers may give the researchers information about you: all current and previous health care providers, including but not limited to the Shirley Ryan AbilityLab (SRALAB), Northwestern Medical Group (NMG), Northwestern Memorial Hospital (NMH), and Northwestern Lake Forest Hospital (NLFH).

Once we have the health information listed above, we may share some of this information with the following offices or entities outside of Northwestern University and its clinical partners (or affiliates): the Northwestern University Institutional Review Board Office and Office for Research Integrity; the US Office of Research Integrity; the US Office for Human Research Protections; the US Food and Drug Administration.

Any research information shared with outside entities will not contain your name, address, telephone or social security number or any other personal identifier unless disclosure of the identifier is necessary for review by such parties or is required by law or University policy [except that such information may be viewed by the Study sponsor and its partners or contractors at the Principal Investigator's office].

The following entities may receive your health information:

- Authorized members of the Northwestern University workforce, who may need to see your information, such as administrative staff members from the Office for Research, Office for Research Integrity and members of the Institutional Review Board.
- Clinical affiliates, including but not limited to the Shirley Ryan AbilityLab (SRALAB), Northwestern Medical Group (NMG), Northwestern Memorial Hospital (NMH), Northwestern Lake Forest Hospital (NLFH), and the Ann & Robert H. Lurie Children's Hospital of Chicago (Lurie Children's). Your participation in this clinical trial may be tracked in an electronic database and may be seen by investigators running other trials that you are enrolled in and by your healthcare providers.
- Clinical affiliates, including but not limited to Northwestern Medical Group (NMG), Northwestern Memorial Hospital (NMH), and Northwestern Lake Forest Hospital (NLFH), for purposes including, but not limited to, the affiliate's provision of care to you and/or the affiliate's scheduling of appointments and/or billing activities.
- Study monitors and auditors who make sure that the study is being done properly,
- Government agencies and public health authorities, such as the National Institutes of Health.

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Those persons who get your health information may not be required by Federal privacy laws (such as the Privacy Rule) to protect it. Some of those persons may be able to share your information with others without your separate permission.

The results of this study may also be used for teaching, publications, or for presentation at scientific meetings.

Unless you revoke your consent, it will expire at the end of the research study.

Although you may revoke consent to participation in this research at any time and in any format, you must revoke authorization for use or disclosure of your health information in writing. To revoke your authorization, write to:

Christina Zelano, PhD
Northwestern University
Department of Neurology
303 E Chicago Ave. Ward Building 13-007, Chicago, IL 60611

You do not have to authorize the use or disclosure of your health information; however, you will not be allowed to take part in this research study. If you do not authorize the use or disclosure of your health information, it will not affect your treatment by health care providers, or the payment or enrollment in any health plans, or affect your eligibility for benefits.

A copy of this signed consent document, information about this study, and the results of any test or procedure done may be included in your medical records and may be seen by your insurance company.

Optional Elements:

The following research activities are optional, meaning that you do not have to agree to them in order to participate in the research study. Please indicate your willingness to participate in these optional activities by placing your initials next to each activity.

I agree	I disagree	
_____	_____	The researcher may audio or video record me to aid with data analysis. The researcher will not share these recordings with anyone outside of the immediate study team.
_____	_____	The researcher may audio or video record me for use in scholarly presentations or publications. My identity may be shared as part of this activity, although the researcher will attempt to limit such identification. I understand the risks associated with such identification.
_____	_____	The researcher may contact me in the future to see whether I am interested in participating in other research studies by the Principal Investigator of this study.

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Signature Block for Capable Adult:

Your signature documents your permission to take part in this research. You will be provided a copy of this signed document.

_____ _____
Signature of Participant Date

_____
Printed Name of Participant

_____ _____
Signature of Person Obtaining Consent Date

_____
Printed Name of Person Obtaining Consent

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

_____ _____
Signature of Witness to Consent Process Date

_____
Printed Name of Person Witnessing Consent Process