Official Title: The Effect of Clear Masks on Patient Satisfaction With Physician Communication During Awake Brain Surgery
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Wake Forest®
School of Medicine

WAKE FOREST School of Medicine
Department of Neurosurgery

Evaluation of patient satisfaction with physician communication during awake brain surgery

Informed Consent Form to Participate in Research
Wesley Hsu, MD, Principal Investigator

SUMMARY

You are invited to participate in a research study. The purpose of this research is to determine patients' satisfaction with a particular aspect of their surgical experience when undergoing deep brain stimulation (DBS) surgery.

You are invited to be in this study because you are undergoing surgery to place deep brain stimulators, during which you will be awake. Your participation in this research will involve one visit which will last about 20 minutes and will be completed when you are here for your surgery.

Participation in this study will involve undergoing DBS placement surgery that you and your doctor have planned for you and then answering a series of questions regarding your opinion on the experience. All research studies involve some risks. A risk to this study that you should be aware of is it may lengthen the time you are in surgery because you will be asked questions, which may take about 10-15 minutes to answer. You may not benefit from participation in this study.

Your participation in this study is voluntary. You do not have to participate in this study if you do not want to. There may be other choices available to you. You will not lose any services, benefits, or rights you would normally have if you choose not to participate.

The remainder of this form contains a more complete description of this study. Please read this description carefully. You can ask any questions if you need help deciding whether to join the study. The person in charge of this study is Dr. Wesley Hsu, MD. If you have questions, suggestions, or concerns regarding this study or you want to withdraw from the study his contact information is:

Wesley Hsu, MD
[redacted]

If you have any questions, suggestions or concerns about your rights as a volunteer in this research, contact the Institutional Review Board at [redacted] or the Research Subject Advocate at Wake Forest at [redacted].

INTRODUCTION

You are invited to be in a research study. Research studies are designed to gain scientific knowledge that may help other people in the future. You are being asked to take part in this study because you are undergoing deep brain stimulation surgery, during which you will be awake. Your participation is voluntary. Please take your time in making your decision as to whether or not you wish to participate. Ask your study doctor or the study staff to explain any words or information contained in this informed consent document that you do not understand. You may also discuss the study with your friends and family.

WHY IS THIS STUDY BEING DONE?

The purpose of this research study is to evaluate patients' experience and satisfaction during the awake deep brain stimulation procedure. Normally, the neurologist will ask you questions and also ask you to perform tasks during surgery. This helps figure out if the stimulators are in the right place in your brain. During this time, the neurologist will be talking to you and you will be responding by answering questions or participating with the tasks. These will include things like:

- Do you notice any weakness in your arm?
- Do you have any tingling in your face?
- Raise your arm in the air.
- Tap your fingers together as fast as you can.

For some study participants, there will be one small change made to the typical way the neurologist conducts this evaluation. We will then ask the study participants about their experience with the neurologist's evaluation. You will not be told what part of the evaluation is changed for the study, until after you have responded to the questionnaire.

HOW MANY PEOPLE WILL TAKE PART IN THE STUDY?

There will be 80 people at Wake Forest Baptist Hospital that will take part in this study.

WHAT IS INVOLVED IN THE STUDY?

If you take part in the study, you will first be asked questions about your hearing.

You will then be randomized into one of two study groups described below. Randomization means that you are put into a group by chance. It is like flipping a coin. You will have an equal chance of being placed in either group. The two groups are:

A – a small change will be made to the way the neurologist conducts the evaluation during your surgery.

B – no change will be made to the way the neurologist conducts the evaluation during your surgery.

After the neurologist's evaluation, both groups will be given a questionnaire regarding their

opinion on the interaction with the neurologist.

You will not be told which group you are in, or what the change is, until the completion of your study participation. The study is complete at the end of the questionnaire. If you wish to know which group you were in or what the change was, you can be told at this point. This is to decrease or avoid bias that may result from you knowing about the change.

There will be no blood or tissue samples collected for this study. You will not be photographed/videotaped/audiotaped.

How Long Will I Be in the Study?

You will be in the study from the time you agree to participate, until you have finished answering the questionnaire. The questionnaire will be completed during the surgery, therefore you will be finished with the study before the end of your surgery. There will be no follow up visits.

You can stop participating at any time. If you decide to stop participating in the study you will just need to say so and you will not be asked any more questions. There are not expected to be any health risks or consequences from withdrawing from the study.

What Are the Risks of the Study?

Being in this study may involve some risk to you. You should discuss the risk of being in this study with the study staff. Risks and side effects related to the study may include a longer time in the operating room to complete the questionnaire. However, this will be minimal and is not expected to cause a significant change to your overall operation experience.

In addition, there is a slight risk of a breach of confidentiality. We will do our best to protect your confidential information. Your questionnaire and study data will be stored without any identifying information about you. There also may be other risks that we cannot predict. You should tell the research staff about all the medications, vitamins and supplements you take and any medical conditions you have. This may help avoid side effects, interactions and other risks.

The risk of harm or discomfort that may happen as a result of taking part in this research study is not expected to be more than in daily life or from routine physical or psychological examinations or tests. You should discuss the risk of being in this study with the study staff.

Taking part in this research study may involve providing information that you consider confidential or private. Efforts, such as coding research records, keeping research records secure and allowing only authorized people to have access to research records, will be made to keep your information safe.

ARE THERE BENEFITS TO TAKING PART IN THE STUDY?

You are not expected to receive any direct benefit from taking part in this research study. We hope the information learned from this study will benefit other people in the future.

WHAT OTHER CHOICES ARE THERE?

You do not have to be in this study to receive treatment. You should talk to your doctor about all the choices you have. Because this is not a treatment study, your alternative is to not participate in this study.

WHAT ARE THE COSTS?

There are no costs to participate in the study.

WILL YOUR RESEARCH RECORDS BE CONFIDENTIAL?

The results of this research study may be presented at scientific or medical meetings or published in scientific journals. Your identity and/or your personal health information will not be disclosed unless it is authorized by you, required by law, or necessary to protect the safety of yourself or others. There is always some risk that even de-identified information might be re-identified.

Participant information may be provided to Federal and other regulatory agencies as required. The Food and Drug Administration (FDA), for example, may inspect research records and learn your identity if this study falls within its jurisdiction.

WILL YOU BE PAID FOR PARTICIPATING?

You will receive no payment or other compensation for taking part in this study.

WHO IS SPONSORING THIS STUDY?

This study is being sponsored by Safe'N'Clear, Inc., Davidson, NC, USA. The sponsor is providing money or other support to Wake Forest University Health Sciences to help conduct this study. The researchers do not, however, hold a direct financial interest in the sponsor or the product being studied.

WHAT ABOUT MY HEALTH INFORMATION?

We will make every effort to keep your Protected Health Information private. We will store records of your Protected Health Information in a cabinet in a locked office or on a password protected computer.

Your personal health information and information that identifies you ("your health information")

may be given to others during and after the study. This is for reasons such as to carry out the study, to determine the results of the study, to make sure the study is being done correctly, to provide required reports and to get approval for new products.

Some of the people, agencies and businesses that may receive and use your health information are the research sponsor; representatives of the sponsor assisting with the research; investigators at other sites who are assisting with the research; central laboratories, reading centers or analysis centers; the Institutional Review Board; representatives of Wake Forest University Health Sciences and North Carolina Baptist Hospital; representatives from government agencies such as the Food and Drug Administration (FDA) or the Office of Human Research Protections (OHRP), the Department of Health and Human Services (DHHS) and similar agencies in other countries.

Some of these people, agencies and businesses may further disclose your health information. If disclosed by them, your health information may no longer be covered by federal or state privacy regulations. Your health information may be disclosed if required by law. Your health information may be used to create information that does not directly identify you. This information may be used by other researchers. You will not be directly identified in any publication or presentation that may result from this study unless there are photographs or recorded media which are identifiable.

Monitors, auditors, IRB or other regulatory agencies will be granted direct access to the participant's original medical record for verification of clinical trial procedures or data, without violating confidentiality of the participant and to the extent permitted by other applicable laws.

If required by law or court order, we might also have to share your Protected Health Information with a judge, law enforcement officer, government agencies, or others. If your Protected Health Information is shared with any of these groups it may no longer be protected by federal or state privacy rules

Any Protected Health Information collected from you in this study that is maintained in the research records will be kept for at least six years after the study is finished. At that time any research information not already in your medical record will either be destroyed or it will be de-identified.

You can tell Dr. Wesley Hsu that you want to take away your permission to use and share your Protected Health Information at any time by sending a letter to this address:

Dr. Wesley Hsu
[redacted]

However, if you take away permission to use your Protected Health Information you will not be

able to be in the study any longer. We will stop collecting any more information about you, but any information we have already collected can still be used for the purposes of the research study.

By signing this form you give us permission to use your Protected Health Information for this study.

If you choose to participate in this study, your medical record at Wake Forest University Baptist Medical Center will indicate that you are enrolled in a clinical trial. Information about the research and any medications or devices you are being given as a participant may also be included in your medical record. This part of the medical record will only be available to people who have authorized access to your medical record. If you are not a patient at this Medical Center, a medical record will be created for you anyway to ensure that this important information is available to doctors in case of an emergency.

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 Web site at any time.

What Are My Rights as a Research Study Participant?

Taking part in this study is voluntary. You may choose not to take part or you may leave the study at any time. Refusing to participate or leaving the study will not result in any penalty or loss of benefits to which you are entitled. If you decide to stop participating in the study we encourage you to talk to the investigators or study staff first to learn about any potential health or safety consequences. The investigators also have the right to stop your participation in the study at any time. This could be because it would be detrimental to administer the questionnaire. Information that identifies you may be removed from the data or specimens that are collected as part of this study and could be used for future research or shared with others without additional consent.

You will be given any new information we become aware of that would affect your willingness to continue to participate in the study.

Clinically relevant research results will not be disclosed to you. Research results will be shared in medical journal publications that would not specifically identify your results.

Whom Do I Call if I Have Questions or Problems?

For questions about the study or in the event of a research-related injury, contact the study investigator, Dr. Wesley Hsu at [redacted]

The Institutional Review Board (IRB) is a group of people who review the research to protect your rights. If you have a question about your rights as a research participant, or you would like

to discuss problems or concerns, have questions or want to offer input, or you want to obtain additional information, you should contact the Chairman of the IRB at [redacted] or the Research Subject Advocate at [redacted].

You will be given a copy of this signed consent form.

SIGNATURES

I agree to take part in this study. I authorize the use and disclosure of my health information as described in this consent and authorization form. If I have not already received a copy of the Privacy Notice, I may request one or one will be made available to me. I have had a chance to ask questions about being in this study and have those questions answered. By signing this consent and authorization form, I am not releasing or agreeing to release the investigator, the sponsor, the institution or its agents from liability for negligence.

Subject Name (Printed):_____

Subject Signature: _____ Date: _____Time:_____ am pm

Person Obtaining Consent (Printed):_____

Person Obtaining Consent:_____ Date:_____ Time:_____ am pm