UNIVERSITY of MARYLAND
THE FOUNDING CAMPUS

RESEARCH CONSENT FORM

Protocol Title: Cranial electric stimulation (CES) to modify suicide risk factors in psychiatric inpatients

Study No.: HP-00065640, Date 5th May 2016
Principal Investigator: Nithin Krishna MD, 410-328-6610, 410-328-5386 (24 hour access)

- You are invited to participate in this research study because you are in the hospital on a psychiatric unit and you have suicidal thoughts or actions related to suicide. In this study we are trying to find out whether a treatment called cranial electric stimulation or CES will help in decreasing the risk factors for suicide. CES involves applying a low level of electricity to your head to stimulate the brain. The specific CES device we will use is called Alpha-Stim®. CES will be used in addition to your usual treatment (medication and group therapy). Findings from this study will help us better understand suicide risk factors and possibly improve individual treatment in reducing suicide risk factors. Your participation in this study is voluntary. You may ask questions at any time.

PURPOSE OF STUDY

- The purpose of the study is to test the effectiveness of CES in the treatment of suicide risk factors such as anxiety, depression, insomnia (problems sleeping), and agitation. We want to find out whether CES along with your regular treatment will help to reduce anxiety, depression, insomnia, and agitation. We also want to find out if CES will decrease your risk for suicide more quickly than only using regular treatment. Alpha-Stim® has been used in the treatment of insomnia, depression, anxiety and agitation by medical teams across the nation. Currently you need a prescription from a health professional to use the Alpha-Stim® device. However, the Food and Drug Administration (FDA) of the USA, the governmental group that regulates medications and medical devices, has recently said that they are considering whether CES devices could be used safely for the treatment of anxiety and insomnia without a prescription or guidance from a health professional. If you choose to participate, you will be asked to use the Alpha-Stim® one hour daily 5 to 7 times per week. By signing this consent form, you are indicating your willingness to participate in this study. This study will take place on the University of Maryland Medical Center (UMMC) adult inpatient psychiatric units, 11West and 12West.
- You will be one of approximately 77 subjects included in this study.

PROCEDURES

- The study design will be randomized and double-blind which means, the treatment you get will be chosen by chance and neither you nor the research team will know which treatment you are getting. You will be randomly assigned by chance to receive either the study CES treatment or the placebo treatment. This is like flipping a coin, so you will have a 50% chance of getting the

real treatment and a 50% chance of getting the placebo treatment. The study treatment will be given with an Alpha-Stim® device that delivers a low level of electrical current (100 microamperes), that most people cannot even feel, through electrodes that clip on to your earlobes. The placebo treatment will be given by an Alpha-Stim® device that looks exactly the same and has electrodes that clip on to your earlobes, but does not deliver any electrical current at all. Each CES session will take one hour and will occur 5 to 7 times a week.

- Rating scales will be administered at the beginning of the study, (i.e., pre-treatment), twice a week and at the end of the study. Rating scales are questionnaires about mood, sleep, anxiety, agitation and side effects. You will be asked questions, which you will answer to the best of your abilities. It will take approximately 40 to 45 minutes to complete all of the rating scales.
- Our estimation is that if you agree to participate in this study it will take approximately 1 hour of CES treatment 5 to 7 times a week and forty five minutes twice a week for rating scale assessments, for a total of up to 8 and one half hours weekly. The length of the study will vary depending on how long you are in the hospital, usually 1- 3 weeks.
- Information from your patient medical record will also be collected for this study.

WHAT ARE MY RESPONSIBILITIES IF I TAKE PART IN THIS RESEARCH?

If you take part in this research, you will be responsible to complete all study procedures as instructed including reporting any side affects you notice. This will involve CES sessions and completion of the rating scales as described above.

POTENTIAL RISKS/DISCOMFORTS:

- The Alpha-Stim® device has been used in many clinical trials and there have not been any serious side effects, only minor ones listed below.
- The most common side effects are not very common and occur in less than 1% of people. These side effects are: (1) tingling or irritation at the earlobes where the ear clips attach and (2) tinnitus which is a ringing or buzzing sensation in the ears. However these side effects occurred in studies that used higher levels of electrical current than we will use in this study. A recent study that used the level of electrical current that we will use in this study (100 microamperes) did not report any side effects. Additionally since this study is examining suicide risk factor there is a possible risk of an increase in suicidal thinking or actions.
- We will ask you twice a week if you are having any possible side effects from the CES. If you think you are having side effects at any time, please report this to study staff.
- We will also ask you twice a week about your suicidal thoughts or actions; we will additionally ask you to inform study staff or your usual clinical team of any suicidal thoughts or actions.
- Loss of confidentiality and privacy is another risk of this study; however, we will use all possible precautions to prevent loss of confidentiality and privacy.
- All data will be stored in a secure location such as a locked office or a locked cabinet. All electronic data on computers will be password protected.
- All study procedures will occur privately in rooms away from other patients.

POTENTIAL BENEFITS

Your participation may help increase our knowledge about suicide risk factors and effective treatment in reducing these risk factors of suicide. It is also possible that use of CES will improve your symptoms and may reduce your suicide risk quicker, although this is uncertain.

ALTERNATIVES TO PARTICIPATION

- The proposed study is an adjunctive treatment which means you will continue to receive your usual treatment--medication and group therapy--in addition to CES or sham treatment. You will not be taken off your usual medications during the course of this study. If you choose not to participate in this study, we will continue your normal treatment as usual and your decision will not affect your care. Your participation is voluntary. There will not be a penalty or loss of benefits for not participating or for withdrawing from the study.

COSTS TO PARTICIPANTS

- There will be no costs to you.

PAYMENT TO PARTICIPANTS

- You will not be paid to take part in the study.

CONFIDENTIALITY AND ACCESS TO RECORDS

- Your medical records will be kept confidential, except for the professionals involved in this study and the clinical staff of UMMC. All records are kept in a locked cabinet in a locked room. Everyone using the study information will work to keep your personal information confidential. Your personal information will not be given out unless required by the law.
- Each participant will be given an anonymous research identification number. A separate research identification number list will be kept and will include the participants' names and the assigned research identification number in a password-protected electronic file, known only to the authorized research team members, and stored in a password protected computer with a secure firewall.
- All paper documents with your name or any other identifying information will be stored in a locked filing cabinet separate from the rest of the paper documents. Only authorized members of the research team will have access to paper documents.
- The data from the study may be published. However, you will not be identified by name. People designated from the institutions where the study is being conducted and people from the sponsor will be allowed to inspect sections of your medical and research records related to the study.
- The monitors, auditors, the IRB, the Food and Drug Administration will be granted direct access to your medical records for verification of the research procedures and date. By signing this document you are authorizing this access.
- Efforts will be made to limit 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 organization.
- 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.

RIGHT TO WITHDRAW

- Your participation in this study is voluntary. You do not have to take part in this research. You are free to withdraw your consent at any time. Refusal to take part or to stop taking part in the study will involve no penalty or loss of benefits to which you are otherwise entitled. If you decide to stop taking part, or if you have questions, concerns, or complaints, or if you need to report a medical injury related to the research, please contact the investigator, Nithin Krishna MD, 410-328-6610.
- If you withdraw from this study, already collected data will not be removed from the study records unless you make a request to remove it. You will be asked whether the investigator can collect data from your routine medical care. If you agree, this data will be handled the same as research data.
- You will be told of any significant new findings which develop during the study which may affect your willingness to participate in the study.

CAN I BE REMOVED FROM THE RESEARCH?

The person in charge of the research study or the sponsor can remove you from the research study without your approval. Possible reasons for removal include failure to follow instructions of the research staff or if the person in charge decides that the research study is no longer in your best interest, the sponsor can also end the research study early. The study doctor will tell you about this and you will have the chance to ask questions if this were to happen.

UNIVERSITY STATEMENT CONCERNING RESEARCH RISKS

The University of Maryland, Baltimore (UMB) is committed to providing participants in its research the rights due them under State and federal law. You give up none of your legal rights by signing this consent form or by participating in the research project. This research has been reviewed and approved by the Institutional Review Board (IRB). Please call the Institutional Review Board (IRB) if you have questions about your rights as a research subject.

Participating in research may result in an injury, as explained above. If you suffer an injury directly related to your participation in this project, UMB and/or one of its affiliated institutions or health care groups will help you obtain medical treatment for the specific injury and provide referrals to other health care facilities, as appropriate. UMB and/or its affiliated institutions or health care groups will not provide you with financial compensation or reimbursement for the cost of care provided to treat a research-related injury or for other expenses arising from a research-related injury. The institution or group providing medical treatment will charge your insurance carrier, you, or any other party responsible for your treatment costs. Please choose the statement that is applicable to your study - If you incur uninsured medical costs, they are your responsibility. The study staff can give you more information about this if you have a study injury.

By signing this Consent Form, you are not giving up any legal rights. If this research project is conducted in a negligent manner and you are injured as a direct result, you may be able to recover the costs of care and other damages from the individuals or organizations responsible for your injury.

If you have questions, concerns, complaints, or believe you have been harmed through participation in this research study as a result of researcher negligence, you can contact members of the IRB or the Human Research Protections Office (HRPO) to ask questions, discuss problems or concerns, obtain information, or offer input about your rights as a research participant. The contact information for the IRB and the HRPO is:

University of Maryland Baltimore
Human Research Protections Office
620 W. Lexington Street, Second Floor
Baltimore, MD 21201
410-706-5037

Signing this consent form indicates that you have read this consent form (or have had it read to you), that your questions have been answered to your satisfaction, and that you voluntarily agree to participate in this research study. You will receive a copy of this signed consent form.

If you agree to participate in this study, please sign your name below.

_____
Participant's Signature

Date:_____

_____
Investigator or Designee Obtaining Consent Signature

Date:_____