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Approved by the Beth Israel Deaconess Medical Center Committee on Clinical Investigations:

Consent Approval Date: 4/27/20

Protocol Number: 2014P-000216

BETH ISRAEL DEACONESS MEDICAL CENTER
APPROVED BY THE
COMMITTEE ON CLINICAL INVESTIGATIONS
04/26/2021
APPROVAL EXPIRATION DATE

INFORMED CONSENT FORM TO TAKE PART IN A RESEARCH STUDY

SUBJECT'S NAME:
TITLE OF RESEARCH PROTOCOL: Treating Deep Seizure Foci with Noninvasive Surface Brain Stimulation
PRINCIPAL INVESTIGATOR: Bernard S. Chang, MD
PROTOCOL NUMBER: 2014P-000216

INTRODUCTION:

Research studies include only people who choose to take part. Please read this consent form carefully and ask the investigators or study staff to explain any words or information that you do not clearly understand. We encourage you to talk with your family and friends before you decide to take part in this research study.

- This is a research study;
- Your participation is voluntary;
- A research study includes only people who choose to take part;
- You may or may not benefit from participating in the study. However, your participation may help others in the future as a result of knowledge gained from the research;
- You may leave the study at any time;
- If you choose not to take part, or if you leave the study, your decision will in no way harm your relationship with any member of the research team or any other individuals at Beth Israel Deaconess Medical Center.

Once you read this consent form and understand what your participation in this study will involve, you will be asked to sign this form if you wish to take part. You will be given a signed copy of the form to keep for your records.

DISCLOSURE OF SPECIAL INTERESTS OF BIDMC AND INVESTIGATORS

This study is being conducted by Bernard S. Chang, MD and is funded by the BIDMC epilepsy unit. Neither BIDMC nor Dr. Chang has any additional interests in this research project.

WHOM TO CONTACT IF YOU HAVE QUESTIONS OR PROBLEMS

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PRINCIPAL INVESTIGATOR'S NAME: Bernard S. Chang, MD
PROTOCOL #: 2014P-000216

If you have any questions, concerns or complaints about this research or experience any problems, you should contact Bernard S. Chang at [617] 667-2889.

PURPOSE

The purpose of this research study is to open up the treatment of repetitive transcranial magnetic stimulation (rTMS) to a much larger population of patients with mesial temporal lobe epilepsy (MTLE) and other forms of epilepsy, who are not currently considered good rTMS candidates.

The device involved in this study, Nexstim eXimia TMS stimulator, is investigational. This means that the study device is still being tested in research studies and is not approved by the Food and Drug Administration [FDA] for the way that it is being used in this study. This particular investigationaldevice, Nexstim eXimia TMS stimulator, has been approved by the FDA for use in other diseases or conditions, but we do not yet know if it is useful or safe as a treatment for MTLE.

STUDY PARTICIPANTS

You have been asked to be in the study because you have been diagnosed with mesial temporal lobe epilepsy (MTLE).

Approximately 30 people will take part in this study at Beth Israel Deaconess Medical Center. A total of 30 people will take part in this study at all study sites.

DESCRIPTION OF STUDY DETAILS

If you agree to be in this study, you will be asked to read and sign this consent form. After you sign the consent form, the following things will happen:

1. Screening Procedures: Screening procedures are tests and procedures that will be done to determine if you are eligible to take part in the research study. For this research study, the screening procedures include:

   Identifying if 1) you have been diagnosed with MTLE; 2) you are 18 to 64 years old; 3) you have had prior brain surgery or exposure to TMS; 4) you have rapidly progressive brain lesions (low-grade gliomas, cystic lesions, mesial temporal sclerosis, or other static or slowly progressive lesions); 5) you are unable to tolerate MRI or TMS; and 6) you are pregnant. The investigator will ask you about these issues to determine whether or not you will be able to participate in this study. Urine may be tested with a standard home pregnancy test at the discretion of the investigators.

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2. Randomization Procedures:

   You will be randomly assigned (like the flip of a coin) to receive either low frequency rTMS or high-frequency rTMS or sham rTMS. You have a one in three chance of receiving any of the therapies. You will not be able to choose the study group to which you will be assigned and you will be blinded to your type of treatment.

3. Research Procedures: If you qualify to take part in this research study, you will undergo these research procedures:

Baseline MRI scanning (1 hour on 1 day)
MRI (magnetic resonance imaging) is a sophisticated diagnostic tool for examining the inside of your body without exposing you to x-rays. Using a large magnet, images of great detail can be created. You will go to an MRI suite at Beth Israel Deaconess Medical Center where you will be asked to remove all jewelry, eyeglasses, and anything else containing metal. You will be asked questions about your medical and surgical history before undergoing this test, because people with metal implants (such as shrapnel, surgical clips, or pacemakers) in their bodies cannot undergo MRI. During the MRI you will lie down on your back on a narrow table. The table will be moved into position inside a large machine shaped like a tube. There is not much room between your body and the top and sides of the tube. During certain parts of the testing, you will be asked to hold completely still for a few minutes and simply relax, without concentrating on thinking about any particular thing or doing any particular task. You will be in voice contact with the MRI staff continuously during this process. If you suffer from claustrophobia or anxiety, you should notify the MRI staff beforehand. If you become uncomfortable during the MRI procedure, you can speak to the staff or activate an emergency button and the testing will be stopped immediately. The total scanning time will be up to one hour. The purpose of this baseline MRI is to identify the locations of the malformations in your brain and identify areas in your brain which are connected to these malformations. The MRI is not meant to diagnose any problems.

Baseline Seizure Diary (12 weeks before first rTMS session)
You will be asked to keep a seizure diary for 12 weeks that will maintain details of all seizures and possible adverse effects.

Pre-rTMS EEG (Day 1: 1 hour)
Electroencephalography (EEG) is a procedure that uses electrodes placed on the scalp to measure electrical potentials in the brain. A cap with electrodes on it will be placed on your head against your scalp with a removable adhesive. You will feel the cap with the electrodes against your scalp, but the process of EEG recording is painless. You will undergo scalp EEG recording during which the investigator will put a cap with EEG electrodes on your head and you will be asked to remain still and quiet for 60 minutes.

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Repetitive Transcranial magnetic stimulation (Day 1-10 (with a 2 day break on days 5 and 6): on average 1.5 hours per day)

Repetitive transcranial magnetic stimulation (rTMS) is a procedure that uses magnetic fields to stimulate the brain. The rTMS device, Nexstim eXimia TMS stimulator, is an experimental device. A large electromagnetic coil will be placed against your scalp, creating short pulses of painless electric currents that stimulate nerve cells in your brain. You will feel a slight tapping sensation on your head. If at any point you become uncomfortable, let the staff know and they will stop the testing immediately.

You will undergo 30 minutes rTMS sessions for 10 consecutive weekdays. The rTMS sessions will stimulate different areas of your brain based on the findings from your baseline MRI.

Post-rTMS EEG (Day 10: 1 hour)

4. Monitoring/Follow-Up Procedures. Procedures performed to evaluate the effectiveness and safety of the research procedures are called "monitoring" or "follow-up" procedures. For this research study, the monitoring/follow-up procedures include:

Follow-Up Seizure Diary (12 weeks after last rTMS session)

After completion of all 10 rTMS sessions, you will be asked to keep a seizure diary for 12 weeks that will maintain details of all seizures and possible adverse effects.

Final EEG (1 hour on 1 day, 12 weeks after last rTMS session)

Follow-Up rTMS Sessions

Subjects may demonstrate individual differences in their response to rTMS. For some subjects, a follow-up session with an alternate rTMS protocol may provide additional information regarding their brains' response to stimulation.
Therefore, after the 12-week follow up period, you may be asked if you wish to return for further rTMS sessions. Subsequent sessions would occur only after the 12-week follow-up period, and the procedures would be comparable to the initial rTMS sessions. The rTMS protocol chosen by the investigators would depend on your seizure frequency response to the first rTMS protocol.

If you return for follow-up rTMS, the procedures would be as follows:

Baseline Seizure Diary (12 weeks before first rTMS session)

You will be asked to keep a seizure diary for 12 weeks that will maintain details of all seizures and possible adverse effects.

Pre-rTMS EEG (Day 1: 1 hour)

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Repetitive Transcranial magnetic stimulation (Day 1-10 (with a 2 day break on days 5 and 6): on average 1.5 hours per day)

Repetitive transcranial magnetic stimulation (rTMS) is a procedure that uses magnetic fields to stimulate the brain. The rTMS device, Nexstim eXimia TMS stimulator, is an experimental device. A large electromagnetic coil will be placed against your scalp, creating short pulses of painless electric currents that stimulate nerve cells in your brain. You will feel a slight tapping sensation on your head. If at any point you become uncomfortable, let the staff know and they will stop the testing immediately.

You will undergo 30 minutes rTMS sessions for 10 consecutive weekdays. The rTMS sessions will stimulate different areas of your brain based on the findings from your baseline MRI.

Post-rTMS EEG (Day 10: 1 hour)

3. Monitoring/Follow-Up Procedures. Procedures performed to evaluate the effectiveness and safety of the research procedures are called “monitoring” or “follow-up” procedures. For this research study, the monitoring/follow-up procedures include:

Follow-Up Seizure Diary (12 weeks after last rTMS session)

After completion of all 10 rTMS sessions, you will be asked to keep a seizure diary for 12 weeks that will maintain details of all seizures and possible adverse effects.

Final EEG (1 hour on 1 day, 12 weeks after last rTMS session)

RISKS AND DISCOMFORTS

As a result of your participation in this study, you are at risk for side effects listed in this section. You should discuss these with the investigator and with your regular doctor if you choose.

More Common

You may experience some tiredness and frustration during the testing. You should feel free to let the study staff know if you are feeling tiredness or any other kind of discomfort.

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Up to 20-40% of individuals undergoing TMS experience headaches or neck pain, which are believed to be due to excessive muscle tension. In the case of such an event, you will be offered acetaminophen, which in prior cases of headache or neck ache induced by TMS has promptly resolved the discomfort.

TMS produces a loud clicking sound that can result in ringing in the ears and short-term decreased hearing if no protection is used. In order to prevent this potential adverse effect, you will be given earplugs, which have been shown to be effective in preventing the risk of hearing disturbance due to TMS. In one case a subject's hearing protection fell out and resulted in permanent hearing loss. If your ear plug loosens, becomes detached or falls out you may be at risk of permanent hearing loss. You should immediately report any loosening or detachment of an earplug during TMS. If this happens, the investigators will immediately stop TMS. You will be promptly referred for auditory assessment if you experience hearing loss, ringing in the ear, or ear fullness following completion of TMS.

<u>Less Common</u>
Some patients experience discomfort inside the MRI machine because they are not comfortable in close spaces and around loud noises. You will be allowed to wear earplugs if you wish, and you will be in constant voice contact with the MRI staff. If you become too uncomfortable, the test can be stopped immediately. If you have experienced claustrophobia (fear of closed spaces) in the past, please let the MRI staff know this.

Some participants may have unexpected abnormalities discovered on brain imaging. Some, but not all, MRI abnormalities may have health implications. If an MRI abnormality is discovered during your participation in this study, you may be referred for a neurological evaluation in the Beth Israel Deaconess Medical Center Neurology Clinic. It may be necessary to undergo a regular brain MRI obtained in the clinical setting. The brain images obtained for the purpose of this research study are limited and do not give the same information as a brain MRI done in a clinical setting. For this reason, a normal MRI in this protocol does not rule out possible brain abnormalities, and participation in this protocol should not be used to diagnose any problems.

If you have epilepsy, it is possible that you could experience a seizure during TMS, although the risk is less than 2% for patients with known epilepsy. Typically, the type of seizure a patient experiences while undergoing TMS is identical to those he or she usually experiences. Most seizures experienced during TMS occurred prior to the development of current safety guidelines, which will be used in this study.

<u>Rare</u>
TMS could induce short-term changes in memory, attention, and other brain functions. However, because the understanding of brain connectivity in the population of patients with mesial temporal lobe epilepsy is limited, the risk for these patients in particular is not clear.

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It is possible that you could faint during the TMS. This does not happen often, but can happen if you are anxious, nervous or have not eaten. You should immediately tell the study staff if you feel "dizzy, lightheaded or that you might pass out." The TMS will be stopped. You will be monitored until you are feeling better.

There is a very small risk (<0.15%) of psychiatric effects such as mania and delusions for patients with medically refractory (not completely controlled by medical therapy) depression or bipolar disorder who receive TMS. Individuals with a current diagnosis of a mood disorder will be excluded from this study.

You may experience dental pain while undergoing TMS. If this happens to you, we ask that you report any such discomfort immediately to the investigator, who will terminate the stimulation session. We encourage you to seek a dental evaluation if you experience any dental discomfort, since this is a very rare occurrence but may point to the presence of a cavity that may require care. This adverse effect is not expected to lead to any lasting problems or complications.

It is important to recognize that the safety of MRI in pregnancy for both the pregnant woman and her fetus has not been definitively established. Therefore, women who are pregnant are excluded from participating in this part of the study. Because the safety of MRI in pregnancy is not clear, MRI is normally only performed on pregnant women in special clinical circumstances, as decided on a case-by-case basis by the woman and her treating physician. If you are pregnant or become pregnant, this MRI may involve risks to the embryo or fetus which are currently unforeseeable.

LOSS OF CONFIDENTIALITY
There is the potential for loss of confidentiality by participating in this study. Every effort will be made to protect the confidentiality of your identifiable information. However, if your participation becomes known, it could create a problem or hardship for you depending upon the type of information disclosed. In some situations, it is possible that you would be placed at risk for legal criminal prosecution or other legal problems. There may also be damage to your future financial standing, health care, employment, professional standing or ability to get access to health or other insurance.

PSYCHOLOGICAL STRESS:
You may become tired or frustrated during the MRI testing, because it requires you to lie still in an enclosed space for a period of time. In addition, you may become uncomfortable in the MRI scanner due to the close space and loud noises, particularly if you experience claustrophobia.

CONFIDENTIALITY

Information learned from your participation in this study and from your medical record may be

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reviewed and photocopied by the Food and Drug Administration (FDA) and/or other federal and state regulatory agencies, and by the device manufacturer, Nexstim, accreditation agencies, the Committee on Clinical Investigations, the Human Subjects Protection Office and others involved in research administration of the Beth Israel Deaconess Medical Center with protection of confidentiality so far as permitted by applicable law. Information resulting from this study and from your medical record may be used for research purposes and may be published; however, you will not be identified by name in such publications.

All records regarding this research project will be stored in the locked office of the PI, in the Comprehensive Epilepsy Center of BIDMC. The data will be stored on paper and on secure computers protected with passwords. The subjects' identity will not be disclosed in publications or presentations. The records of the research project are open only to authorized monitors from the BIDMC CCI, and the FDA.

POSSIBLE BENEFITS

It is not possible to predict whether you will benefit directly from participation in this study. There is a possibility that you would benefit from improved seizure control and frequency as a result of treatment of rTMS. Your participation may help others in the future as a result of knowledge gained from the research.

OTHER AVAILABLE OPTIONS

Taking part in this study is voluntary. Instead of being in this study, you have the following options:

> The alternative to participating in this research study is to choose not to participate. You may also withdraw from the study at any time, should you change your mind about participating.

Participation in this research study does not take the place of routine physical examinations or visits to your regular doctor.

We recommend that you discuss these and other options with the investigator and your regular doctor so that you can make a well-informed decision about participating in this study.

IF YOU DECIDE NOT TO TAKE PART IN THE STUDY

Participation in this study is voluntary. You have the right to decide not to take part in this study. If you choose to participate, you have the right to leave the study at any time. Your decision to not participate will not result in any penalties or loss of benefits to you. The investigators will tell you about new information that may affect your willingness to stay in this study.

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If you decide not to participate in the study or decide to leave the study early, your decision will not affect your relationship with the research team or any other individual at Beth Israel Deaconess Medical Center.

INVESTIGATORS RIGHT TO STOP THE STUDY

The investigators have the right to end your participation in this study if they determine that you no longer qualify to take part, or if it would be dangerous for you to continue, or if you do not follow study procedures as directed by the investigators. Beth Israel Deaconess Medical Center or the funding source may stop the study at any time.

COSTS AND/OR PAYMENTS TO YOU

COSTS COVERED BY STUDY
You will not be charged for any tests of procedures that are part of this research study.

CO-PAYMENT/DEDUCTIBLE STATEMENT
You will be responsible for any co-payments or deductibles that are standard for your insurance coverage.

COST OF RESEARCH RELATED INJURY:
If you are injured as a direct result of your participation in this study, you should contact the Investigator at the number provided under the section “Who to Call if You Have Questions” in this form. You will be offered the necessary care to treat your injury. We reserve the right to bill your insurance company or the sponsor, if appropriate, for the care you get for the injury. We will try to get these costs paid for, but you may be responsible for some of them. You may be responsible for all co-payments and deductibles required under your insurance. At this time there is no plan to reimburse you for items such as lost wages or lost time from work. By signing this consent form you have not given up any legal rights.

OTHER IMPORTANT INFORMATION

A description of this clinical trial will be available on www.ClinicalTrials.gov as required by U.S. law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time

AUTHORIZATION FOR USE AND DISCLOSURE OF YOUR PROTECTED HEALTH INFORMATION
As part of this study, we will be collecting, using and sharing with others information about you.

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Please review this section carefully as it contains information about the federal privacy rules and the use and disclosure of your information.

PROTECTED HEALTH INFORMATION [PHI]
By signing this informed consent document, you are allowing the investigators and other authorized personnel to use [internally at BIDMC] and disclose [to people and organizations outside the BIDMC workforce identified in this consent] health information about you. This may include information about you that already exists (for example: your medical records and other sources of health information, demographic information, the results of any laboratory tests, as well as any new information generated as part of this study. This is your Protected Health Information.

PEOPLE/GROUPS AT BIDMC WHO WILL SHARE AND USE YOUR PROTECTED HEALTH INFORMATION
Your Protected Health Information may be shared with and used by investigators listed on this consent form as well as the supporting research team [i.e. research assistants and coordinators, statisticians, data managers, laboratory personnel, pharmacy personnel, administrative assistants], and may also be shared and used by other health care providers at BIDMC who have treated you in the past and have information relevant to the research, or who provide services to you in connection with the research. Your Protected Health Information may also be shared with the members and staff of the Committee on Clinical Investigations of Beth Israel Deaconess Medical Center, which is responsible for reviewing studies for the protection of the research subjects.

PEOPLE/GROUPS OUTSIDE OF BIDMC WITH WHOM YOUR PROTECTED HEALTH INFORMATION WILL BE SHARED
We will take care to maintain confidentiality and privacy about you and your Protected Health Information. We may share your Protected Health Information with the following groups so that they may carry out their duties related to this study:

- The funding source and/or sponsor of this study and, where applicable, the people and companies that the funding source and/or sponsor use to oversee, administer, or conduct the research (for example, clinical research organizations are companies that are sometimes hired by research sponsors to help manage and run a clinical research study)
- The other hospitals and medical centers taking part in this study and research collaborators at those institutions
- Any external health care providers who provide services to you in connection with this research
- Laboratories not affiliated with BIDMC that are involved in conducting tests related to the research
- Statisticians and other data monitors not affiliated with BIDMC
- The members and staff of any other IRBs (beyond the BIDMC Committee on Clinical Investigations) that oversee the research

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- Centralized data collectors
- Your health insurance company
- The Food and Drug Administration [FDA], the Department of Health and Human Services [DHHS], the National Institute of Health [NIH], the Office for Human Research Protections [OHRP], and other federal and state agencies that may have jurisdiction over the research
- Hospital and Clinical Research Accrediting Agencies
- Data and Safety Monitoring boards that oversee this study (if applicable)

Those who receive your Protected Health Information during the course of the research may not be required by the federal privacy regulations to protect it, and they may make further disclosures to others and use your information without being subject to penalties under those laws.

WHY WE ARE USING AND SHARING YOUR PROTECTED HEALTH INFORMATION

The main reason for using and sharing your Protected Health Information is to conduct and oversee the research as described in this Informed Consent Document. There are many other reasons beyond the research for which BIDMC may use or disclose your Protected Health Information. Not all of these reasons require your express written authorization. For example, we will use and share your Protected Health Information to ensure that the research meets legal, institutional and accreditation requirements and to conduct public health activities. The various ways in which BIDMC may use and disclose your protected health information without your authorization are explained in a document called the Notice of Privacy Practices. If you have not received a copy of BIDMC's Notice of Privacy Practices, please ask us for one and review it before signing this form. In addition to signing this document, you may also be asked to sign a BIDMC General Agreement form acknowledging that you have received the BIDMC Notice of Privacy Practices.

Medical Record

A copy of this consent form and information collected during this research may become part of your medical record, if the information is relevant to the care you receive at Beth Israel Deaconess Medical Center. Medical records are considered permanent records; therefore, information cannot be deleted from the record. Medical records are available to health care professionals at Beth Israel Deaconess Medical Center and may be reviewed by staff when carrying out their responsibilities, as well as by external parties such as health care insurers and others in certain circumstances. If you are not currently a patient at Beth Israel Deaconess Medical Center and do not have a medical record at Beth Israel Deaconess Medical Center, one may be created for you for your participation in this research. You may also be required to register as a patient of Beth Israel Deaconess Medical Center in order to participate in this research.

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NO EXPIRATION DATE – RIGHT TO WITHDRAW AUTHORIZATION

Your authorization for the use and disclosure of your Protected Health Information in this Study shall never expire. However, you may withdraw your authorization for the use and disclosure of your Protected Health Information at any time provided you notify the Principal Investigator in writing. If you would like to take back your authorization so that your Protected Health Information can no longer be used in this study, please send a letter notifying the Principal Investigator of your withdrawal of your authorization to Bernard S. Chang at 330 Brookline Ave., Boston, MA 02215. Please be aware that the investigators in this study will not be required to destroy or retrieve any of your Protected Health Information that has already been used or disclosed before the Principal Investigator receives your letter, and they are permitted to continue to use and disclose your previously collected information as necessary to complete the research.

REFUSAL TO SIGN

Your clinical treatment may not be conditioned upon whether you sign the Authorization for Research. However, if you choose not to sign this informed consent document and authorization for the use and disclosure of your Protected Health Information, you will not be allowed to take part in the research study.

RIGHT TO ACCESS AND COPY YOUR PHI

If you wish to review or copy your Protected Health Information as it is made part of your medical record, you may do so after the completion or termination of the study by sending a letter to the Principal Investigator requesting a copy of your Protected Health Information. You may not be allowed to inspect or copy your Protected Health Information until this study is completed or terminated.

ADDITIONAL CONTACT FOR QUESTIONS OR CONCERNS

If you have any questions about this research or experience any problems, you should contact Bernard S. Chang. M.D., at [617] 667-2889.

You may contact the Human Subjects Protection Office at [617] 975-8500 in the event that you would like to obtain information or to offer input about the research study. This office is independent of the investigator or investigator's research staff and can also assist with questions relating to your rights as a participant in research, which may include questions, concerns or complaints about your participation in the study.

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THE FOLLOWING PARAGRAPHS CONTAIN SOME STANDARD INFORMATION WHICH GENERALLY APPLIES TO INDIVIDUALS PARTICIPATING IN A RESEARCH STUDY.

CONSENT FORM FOR CLINICAL RESEARCH

I have read the previous page[s] of the consent form and the investigator has explained the details of the study. I understand that I am free to ask additional questions.

If I wish additional information regarding this research and my rights as a research subject, or if I believe I have been harmed by this study, I may contact the Human Subjects Protection Office (HSPO).

I am aware that this is a research project and that unforeseen side effects may occur.

I understand that the Beth Israel Deaconess Medical Center has no formal program for compensating patients for medical injuries arising from this research. Medical treatment will be provided for injuries at the usual charge to me or to my insurer unless payment is otherwise provided for in this consent form.

I understand that participation in this study is voluntary and I may refuse to participate or may discontinue participation at any time without penalty, loss of benefits, or prejudice to the quality of care which I will receive.

I acknowledge that no guarantees have been made to me regarding the results of the treatment involved in this study, and I consent to participate in the study and have been given a copy of this form.

_____ _____

Signature of Subject or Legally Authorized Representative (Parent if the subject is a minor)

Date

_____

Relationship of Legally Authorized Representative to Subject

The subject has been given the opportunity to read this consent form and to ask questions before signing, and has been given a copy.

_____

SIGNATURE OF INVESTIGATOR/Co-Investigator DATE

_____

PRINT INVESTIGATOR'S/Co-Investigator's NAME

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THE FOLLOWING SECTIONS ARE NOT NEEDED FOR ALL STUDIES AND SHOULD BE UTILIZED AS INDICATED:

If the subject is able to speak and understand English but is not able to read or write

I was present during the entire oral presentation of the informed consent and witnessed the subject's agreement to participate in the study.

Signature of Witness: _____

Printed Name of Witness: _____

Date: _____

If the subject is able to understand English but is not physically able to read or write or see

I was present during the entire oral presentation of the informed consent and witnessed the subject's agreement to participate in the study.

Signature of Witness: _____

Printed Name of Witness: _____

Date: _____

If the subject is not English speaking and signed the translated Short Form in lieu of the English consent document.

As someone who understands both English and the language spoken by the subject, I interpreted, in the subject's language, the researcher's presentation of the English consent form. The subject was given the opportunity to ask questions.

Signature of Interpreter: _____

Printed name of Interpreter: _____

Date: _____