**CONSENT TO PARTICIPATE IN A
RESEARCH STUDY AT THE CHILDREN'S MERCY HOSPITALS**

Repeated Oscillatory Transcranial Magnetic Stimulation therapy of the Epileptogenic Cortical

Area in Children with Focal Continuous-Spike and Wave during Sleep.

SUMMARY

We are asking you to be in this research study. Being in a research study is completely voluntary, and your choice will not affect your regular medical care. This research study is done to test a new device that uses magnetic stimulation to treat a specific type of childhood epilepsy. The following things are part of this study: a medical chart review, questionnaires, vital signs, physical exam, and wearing the device (a cap) on the head for approximately 10 minutes. Being in this study will take place during your scheduled admission to the Epilepsy Monitoring Unit (EMU). The biggest risks from being in this study are flashing lights, numbness or thumb twitching, headache or seizure. There may/may not be direct benefit to being in this study: There is a possibility the device may decrease your spike wave index, the measurement of abnormal brain activity. The device might or might not help with your seizure management by decreasing your spike wave index. Instead of being in this study, you can continue to get regular medical care.

WHO IS DOING THIS STUDY?

A study team led by Dr. Lalit Bansal, MD is doing this study. Other health care professionals may help him.

Funding for this study comes from Children's Mercy Hospital Department of Neurology. The study team will not receive any personal payment because of your decision.

We are asking you to be a part of this research study. Please read the information below and ask questions about anything that you do not understand before you make a choice.

WHY IS THIS STUDY BEING DONE?

Continuous Spike and Wave during Sleep (CSWS) is a rare neurological disease with a rate of 2-5 per 1000 children with childhood epilepsy. It is often accompanied damage to the brain and developmental problems. While it can be treated with drugs, other treatments are being tested. One noninvasive treatment that is being tested is called Transcranial Magnetic Stimulation Therapy. It produces repetitive stimulation with magnets when applied to the head. This treatment has been used for a number of years, but the device used for the treatment is bulky and required a high strength magnet. A new device has been developed that is portable, wearable and the stimuli it produces are much milder. It is called Multisite Transcranial Magnetic Stimulation m(TMS). It can deliver stimulation to multiple areas of the brain or stimulate one area at a time. The purpose of this research study is to see if this new device can help children and young adults between the ages of 3 and 21 years of age who have focal CSWS that are uncontrolled by current drugs.

The Repetitive Trans Magnetic Stimulator device r(TMS) is a FDA approved device currently used to treat severe neurological and psychiatric conditions such as stroke, major depression, migraine, epilepsy, movement disorders and Tourette Syndrome in adults. However, the model used in this study, the Multisite Transcranial Magnetic Stimulator m(TMS) has been changed slightly. Therefore, it is called an investigational device for this study because we are still learning about its use in this new design. "Investigational" means that it is still experimental and has not been approved yet for this use by any regulatory agency, including the FDA.

WHO CAN BE IN THIS STUDY?

We are asking you to be a part of this research study because you have been diagnosed with focal CSWS.

Up to 10 children and adults between the ages of 3 and 21 years will be asked to be in this study at The Children's Mercy Hospitals.

WHAT WILL HAPPEN TO ME IN THIS STUDY?

Being in this study involves a review of your medical record, filling out questionnaires and having the device (cap) placed on your head one time only for 10 minutes. If you agree to be in this study, you will be in this study for one day. Results of this study will be evaluated by the Principle Investigator. Your identity will not be shared.

This study is a study looking at how effective this device is, which means that you will receive the live magnetic stimulation from the study device.

If you decide to be in this study, the following things will happen:

A picture of the device on your head will be taken prior to each treatment. No identifiable information will be captured. This is to ensure correct and consistent placement of the device.

This visit will take about 1 hour to complete

- Your participation will involve collecting the following information:
    - Review of your medical history (including Date of Birth, ethnicity and gender)
    - Medication history
    - Current medications
    - Vital signs (blood pressure, pulse, respiration rate, and temperature)

- You do not have to give any information to the study that you do not want to give. By signing this form you are authorizing the collection and use of the information outlined above. Information above collected for this study will be shared with the study staff.

- You will be asked to complete a questionnaire on an electronic device called the DIMFAST. This questionnaire asks you about how you feel before and after the treatment and takes about 5 minutes to complete.

- You will be asked to wear the mTMS device for 10 minutes.

WHAT ARE THE RISKS OF THE STUDY?

There are certain risks in this study. These risks may include the following:

There is the possibility you will experience flashing lights, numbness or thumb twitching during the use of the device. You may hear the sound of a tiny motor while wearing the device. You may experience the sensation of mild vibrations to the scalp while wearing the device.

There is a slight risk of loss of confidentiality. Your confidentiality will be protected to the greatest extent possible.

The following is a table of possible risks and discomforts:

Rare, occurring in less than 2% of patients	**Common, occurring in 25% to 40% of patients**
Seizure in non-epileptic children/adults	Headache
Bipolar activity in children/adults diagnosed with bipolar disorder.	Other nonspecific pain and/or discomfort.

If you have any of these problems or changes in the way you feel, you should tell the investigator or other study personnel as soon as possible.

There may be risks we don't know about right now. We will tell you about any new information that might change your decision to stay in the study.

WHAT ARE THE BENEFITS OF BEING IN THIS STUDY?

Taking part in this research study might benefit you. There is a possibility the device may decrease your spike wave index. The device might or might not help with your seizure management by decreasing your spike wave index. Your condition may get better, get worse, or stay the same. Your participation may also give more scientific information about the use of this device in management of CSWS.

WHAT ABOUT EXTRA COSTS?

- Participation in this study will not result in any extra costs to you.
- You will not have to pay anything extra in this study aside from the personal time.
- Some of the services or items in this study such as the EMU admission, physician exams, EEG's are also part of the regular treatment for your condition. These services or items would be provided even if you are not in this study. The costs for these services or items will be billed to your insurer. You will be responsible for any such costs your insurer does not cover. If you are uninsured, you will be responsible for these costs. If you have any questions about these costs, or what out-of-pocket expenses you may be responsible for, contact a member of the study team.
- Neither you nor your insurer will be billed for the costs of any services or items that are required by the study but are not considered part of your regular treatment.

WHAT ABOUT CONFIDENTIALITY?

You have rights regarding the privacy and confidentiality of your health information. When health information includes identifiers (like names, addresses, phone numbers and social security or individual taxpayer identification (ITIN) numbers) that link it directly to an individual, it is called protected health information (PHI). Federal laws require that PHI be kept secure and private. In certain situations, federal law also requires that you approve how your PHI is used or disclosed. A research study is one of those situations.

By signing this consent form, you are permitting the following people to have access to your medical record and use your PHI for the research purposes described in this form. You are also permitting your PHI to be shared with everyone listed below:

- The research team, which includes the study personnel listed on this form and other persons involved in this study at The Children's Mercy Hospitals;
- The Institutional Review Board at The Children's Mercy Hospitals;
- A group that oversees the data (study information) and safety of this research;
- People from organizations that provide independent accreditation and oversight of hospitals and research;
- Government/regulatory agencies (both US and international), such as the Office for Human Research Protections and the Food and Drug Administration (FDA).

The research record is separate from your medical record. Information about you that is obtained during this study will be recorded in a research record and may also be recorded in your medical record. A research record will be created and kept in the Department of Neurology research office. The research record may include documents that have your name, assigned study ID number, medical record number, hospital account number, date of birth, dates of service. All research records will be maintained in a confidential manner.

There will be a separate database in which all study information is collected. This database will be used to analyze the study information and find out the study results. Information in this database will include your assigned study ID number.

By signing this consent form, you are allowing your health information to be recorded in the research record. You are also permitting your research record to be shared with everyone listed above.

Some people or groups who get your identifiable health information might not have to follow the same privacy rules that we follow. We will share your health information only when we must, will only share the information that is needed, and will ask anyone who receives it from us to protect your privacy. However, once your information is shared outside of CMH, we cannot promise that it will remain private.

You may choose not to sign this consent form and not be in the study. You may cancel your permission to use and share your PHI at any time by contacting the study personnel listed on this form. You may also contact The Children's Mercy Hospitals Health Information Management (HIM) in writing. If you cancel your permission, you may no longer participate in this study. Your PHI that has already been collected for the study may still be used; however, no new information will be collected except information related to adverse events or other safety issues.

If you do not cancel your permission, your PHI may continue to be recorded until the entire study is finished. This may take years. Any study information recorded in your medical record will be kept forever. Unless stated elsewhere in this form, you may not have access to your research record or research test results.

Results of this study may be made public. If made public, you will not be identified in any publications or presentations.

WHAT ARE THE ALTERNATIVES TO BEING IN THIS STUDY?

Instead of being in this study, you may receive conventional treatment for CSWS.

WHAT ARE MY RIGHTS AS A STUDY PARTICIPANT?

Being in a research study is voluntary. You do not have to be in this study to receive medical care. If you choose not to participate, there will be no penalty or loss of benefits to which you are otherwise entitled.

You may withdraw from the study at any time without penalty or loss of benefits to which you are otherwise entitled. We will inform you of any new information that develops during this study. This information may affect your decision to stay in the study. If you choose to withdraw from the study or if you are asked by personal doctor to withdraw from the study, you must tell the study team as soon as possible.

If you withdraw from the study early for any reason, the information that already has been collected will be kept in the research study and included in the data analysis. No further information will be collected for the study.

Dr. Bansal, the Institutional Review Board or the FDA may stop the study at any time. The investigator(s), or your doctor, may remove you from the study at any time without your permission.

If you withdraw yourself or you are removed from the study for any reason, the study doctor may ask you if they may continue to follow you for monitoring. This visit could include any of the assessments/tests mentioned earlier and any other procedures that the study doctor feels are necessary for your safety.

WHO SHOULD I CALL IF I HAVE QUESTIONS OR PROBLEMS?

You may contact the study team or the IRB at the information above with questions or concerns at any time during the study.

You should call Dr. Bansal if you believe that you have suffered injury of any kind or are sicker as a result of being in this research study.

You may also call the Children's Mercy Hospitals' Pediatric Institutional Review Board (IRB) with questions or complaints about this study. The IRB is a committee of physicians, statisticians,

researchers, community advocates, and others that ensures that a research study is ethical and that the rights of study participants are protected.

SPONSOR AND INSTITUTIONAL RESPONSIBILITIES

In the case of illness or injury resulting from this study, treatment is available at The Children's Mercy Hospitals, but will be provided at the usual charge. Payment for this treatment will be your responsibility. The hospital may not bill insurance or other third party payers for this care. The Children's Mercy Hospitals does not have funds set aside to pay research participants if the research results in injury. By signing this form, you are not giving up any legal rights to seek compensation for injury.

CONSENT OF SUBJECT

The purposes, procedures, and risks of this research study have been explained to me. I have had a chance to read this form and ask questions about the study. Any questions I had have been answered to my satisfaction. I consent to be in this research study. A copy of this signed form will be given to me.

_____	_____	_____
Signature of Adult/Legally Authorized Representative	Date	Relationship to Participant

STUDY PERSONNEL

I have explained the purposes, procedures, and risks involved in this study in detail to:

_____
Print name(s) of Parents/ Legally Authorized Representative, and

_____	_____	_____
Signature of Person Obtaining Permission/Assent	Date	Time

Print Name of Person Obtaining Permission/Assent _____