Medical College of Wisconsin and Froedtert Hospital
CONSENT TO PARTICIPATE IN RESEARCH

Name of Study Subject: _____

INTRA- AND POST-OPERATIVE MEASURES OF AUDITORY FUNCTION

Michael S. Harris, MD
Otolaryngology
(414) 955-0822
Medical College of Wisconsin
8701 Watertown Plank Road
Milwaukee WI 53226

You are invited to take part in this research study. This form tells you why this research study is being done, what will happen in the research study, and possible risks and benefits to you. If there is anything you do not understand, please ask questions. Then you can decide if you want to join this study or not.

A1. INTRODUCTION – WHY ARE WE ASKING YOU ABOUT THIS STUDY?

You are invited to participate in this research study because you are getting a cochlear implant.

A total of about 192 people are expected to participate in this study nationally including about 40 at the Medical College of Wisconsin/Froedtert Hospital.

The Director of the study is Dr. Michael Harris in the Department of Otolaryngology. A study team works with Dr. Harris. You can ask who these people are.

Advanced Bionics is providing reimbursement for this study. Dr. Harris is a consultant for Advanced Bionics.

A2. DO I HAVE TO BE IN THIS STUDY?

You can decide whether to take part in this study or not. You are free to say yes or no. If you say no, your regular medical care will not change. Even if you join this study, you do not have to stay in it. You may stop at any time.

A3. WHY IS THIS RESEARCH STUDY BEING DONE?

The purpose of this study is to see how the inner ear responds to sound delivered to the ear canal during and after your cochlear implant surgery. This information may be helpful in telling us how well a cochlear implant performs after surgery.

B1. WHAT WILL HAPPEN IF I TAKE PART IN THE STUDY?

During the study, you will have measurements taken from your inner ear, mainly the cochlea, both during and after surgery. The cochlea is the part of the inner ear that transforms sound waves into electrical signals that can be processed by your brain.

Because no one knows which of the interventions is best, you will be "randomized" into one of the two groups. One group will be standard of care and the ECochG responses will be off and one group will have the audible ECochG response on and available to the surgeon. 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. Neither you nor the research doctor can choose what group you will be in. Since the expectations of patients and doctors can influence the results, neither you nor your research doctor can know which group you will get until the research is over. A computer program chooses which group you are in, and the procedure in each group will look the same. In an emergency, your research doctor can find out which group you are in.

If you decide to take part in this study, your surgery will take place in the routine way with the following tests added for this research study: Before and after the cochlear implant electrode is put in the inner ear, we will measure inner ear signals with the tests listed below. These tests will add around 15 minutes to the length of your surgery. Similar testing will be done during routine cochlear implant follow-up visits until about 12 months after surgery. These tests will add around 5-15 minutes to each follow-up visit.

The following tests will be done for research:

CT scan 2-3 weeks after surgery.

Electrocochleography (ECochG)- during cochlear implant surgery:
After you have been put to sleep for your cochlear implant surgery, a foam-tipped earphone will be placed in the ear that will be implanted. As the cochlear implant electrode is put in the inner ear, a series of short sounds will be played into your ear, and the response from your inner ear will be measured through cochlear implant. This testing will allow the doctor to observe the condition and function of your cochlea during the surgery.

Electrocochleography (ECochG) and hearing tests- after cochlear implant surgery:
During routine follow-up clinic visits (Activation, 3 months, and 1 year after Activation), a small earphone will be placed in your ear canal, and your cochlear implant will be hooked-up to a computer. A series of short sounds will be played into your implanted ear and the responses will be measured through your cochlear implant. This testing will help us observe the status of your cochlea after surgery. You will also have hearing tests during these appointments. These additional tests will add about 15 minutes to the appointments.

B2. HOW LONG WILL I BE IN THE STUDY?

You will be in this research study for about 15 months total

B3. CAN I STOP BEING IN THE STUDY?

You may stop at any time. If you decide to leave the study, please let the study team know.

The study investigator may stop your participation in the study at any time for any reason without your consent. He will tell you if this happens.

C1. WHAT RISKS OR PROBLEMS CAN I EXPECT FROM THE STUDY?

We watch everyone in the study for unexpected problems. You need to tell the Dr. Harris or a member of the study team immediately if you experience any problems or become too upset.

The risks associated with this study include the added surgical time (around 15 minutes) to complete the research tests during surgery. You will be closely monitored by the anesthesia team, and if any concerns about your health arise, study activities will be stopped.

Post-operative CT scan: Additional radiation exposure. A CT scan is a computerized series of detailed pictures of areas inside the body taken from different angles. This is about half the amount of natural radiation everyone is exposed to in a year.

Another risk may be a potential loss of confidentiality. Every effort will be made to keep your study records confidential but we cannot guarantee it. Depending on the kind of information being collected, if your study information were accidentally seen, it might be used in a way that could embarrass you or affect your ability to get insurance. If you have questions, you can talk to the study director about whether this could apply to you.

C2. ARE THERE ANY BENEFITS TO TAKING PART IN THE STUDY?

You will not likely benefit from taking part in this study.

We may gain new knowledge about the relation between inner ear electrical activity in response to sound during cochlear implant surgery and post-operative outcomes.

D1. ARE THERE ANY COSTS TO BEING IN THE STUDY?

The study will pay for research-related items or services that are provided only because you are in the study.

You or your health plan will pay for all the things you would have paid for if you received a cochlear implant but were not enrolled in this study, such as

- The cochlear implant system, including the internal device and external components (speech processor, remote, and accessories).

- Health care given during the study as part of your regular care such as that needed to program the speech processor and evaluate performance with the device
- Items or services needed to give you study drugs or devices
- Monitoring for side effects or other problems
- Deductibles or co-pays for these items or services.

If you participate in this research study, the costs of any necessary emergency medical treatment in the event of a research-related injury will be billed to you or your health insurance.

D2. WILL I BE PAID FOR BEING IN THE STUDY?

Upon completion of all five study visits, you will receive compensation of $100 (in the form of a VISA or MasterCard pre-paid card) for your participation in this study. In case of early withdrawal from the study, you will be compensated $20 per interval completed.

You will receive roundtrip mileage at $0.54 per mile for the CT scan appointment. The check will be mailed to you within a few weeks after the appointment.

D3. WHAT OTHER CHOICES DO I HAVE?

You do not have to join this study. You are free to say yes or no. Whether or not you join this study, your usual medical services will not change.

D4. WILL I BE GIVEN NEW INFORMATION ABOUT THE STUDY?

If we learn any important new information that might change your mind about being in the study, we will tell you about it right away. You can then decide if you want to stay in the study.

D5. WHAT HAPPENS IF I AM INJURED BECAUSE I TOOK PART IN THE PROJECT?

Emergency medical treatment for injuries directly related to your participation in this research project will be provided to you. You or your health insurance will be billed for the costs of this emergency treatment. MCW will decide on a case by case basis if they will reimburse you or your insurer for emergency treatment costs. If your research-related injury requires medical care beyond this emergency treatment, you or your insurer will be responsible for the costs of this follow-up care.

At this time, there is no plan for any additional financial payments.

If you believe that you have been injured because of your participation in this project, contact the research doctors right away. Contact information: Dr. Harris, (414) 955-0822.

D6. WHO CAN ANSWER MY QUESTIONS ABOUT THE STUDY?

If you have more questions about this study at any time, you can call Dr. Harris at (414) 955-0822.

If you have questions about your rights as a study participant, want to report any problems or complaints, obtain information about the study, or offer input you can call the Medical College of Wisconsin/Froedtert Hospital Research Subject Advocate at 414-955-8844.

E. PERMISSION TO COLLECT, USE AND SHARE HEALTH INFORMATION

E1. What health information will be collected and used for this study?

To be in this research study, the study team needs your permission to access, collect and use some of your health information. If you say no, you cannot be in the study. This information may come from questions we ask, forms we ask you to fill out, or your medical record, as described below. We will only collect and use information needed for the study.

The protected health information (PHI) originates from services you will or have received at one or more of the following locations: the Medical College of Wisconsin (MCW); BloodCenter of Wisconsin (BCW); Children's Hospital of Wisconsin (CHW); any Froedtert Health Affiliate- Froedtert Memorial Lutheran Hospital (FMLH), Inc.; Community Memorial Hospital (CMH) Menomonee Falls, Inc.; St. Joseph's Community Hospital (SJH) West Bend, Inc.; Froedtert & The Medical College of Wisconsin Community Physicians Clinics, Inc. (FMCWCP); the West Bend Surgery Center, LLC; and the Froedtert Surgery Center, LLC.

The health information we will collect and use for this study is:

- Health information collected during this study
- Your Audiology records
- CT scans

E2. Who will see the health information collected for this study?

The only people allowed to handle your health information are those on the study team at MCW/Froedtert Hospital those on the Institutional Review Board (IRB) and those who check on the research activities to make sure the hospital's rules are followed.

If the costs of any necessary emergency medical treatment in the event of a research-related injury are billed to your health insurance, your health information may need to be disclosed to the insurer for billing purposes.

We may record your research information, including results of tests, procedures or questionnaires done for research, in your Froedtert Hospital and/or Medical College of Wisconsin medical record. As a result, this research information may be seen by

people allowed to see your medical records for healthcare operations or treatment, by those you allow to see your medical records by giving written permission, and by others when required by law.

We will not use your health information for a different study without your permission, or the permission of a hospital research review board (IRB). Once all personal identification is removed, the information might be used or released for other purposes without asking you. Results of the study may be presented in public talks or written articles, but no information will be presented that identifies you.

Because this study involves the use of drugs and/or devices, the FDA also has the right to inspect all study records.

E3. What are the risks of sharing this health information?
One risk of taking part in a research study is that more people will handle your personal health information collected for this study. The study team will make every effort to protect the information and keep it confidential, but it is possible that an unauthorized person might see it. Depending on the kind of information being collected, it might be used in a way that could embarrass you or affect your ability to get insurance. If you have questions, you can talk to the study director about whether this could apply to you.

E4. How long will you keep the health information for this study?
If you sign this form, we plan to keep your information for 10 years after the research study ends in case we need to check it again for this study.

E5. Can I cancel my permission to share this health information?
If you change your mind later and do not want us to collect or share your health information, you need to send a letter to Dr. Harris at 8701 W Watertown Plank Rd., Milwaukee, WI 53226. The letter must say that you have changed your mind and do not want the researcher to collect and share your health information. At that time, we may decide that you cannot continue to be part of the study. We may still use the information we have already collected.

CONSENT TO PARTICIPATE IN THE STUDY

By signing my name below, I confirm the following:

- I have read (or had read to me) this entire consent document. All of my questions have been answered to my satisfaction.
- The study's purpose, procedures, risks and possible benefits have been explained to me.
- I agree to let the study team use and share the health information and other information gathered for this study.
- I voluntarily agree to participate in this research study. I agree to follow the study procedures as directed. I have been told that I can stop at any time.

IMPORTANT: You will receive a signed and dated copy of this consent form. Please keep it where you can find it easily. It will help you remember what we discussed today.

Subject's Name *please print*	**Subject's Signature**	**Date**
Name of Witness (if applicable**)** *please print* (for short form consent process, or consent of blind or illiterate subject)	**Signature of Witness**	**Date**