

**University of Wisconsin-Madison/Medical College of Wisconsin**

**Research Subject Information and Consent Form**

**Title of Study: Atomic Biomagnetometer for Fetal Biomagnetism**

**Study Investigators: Prof. Thad Walker (UW), Prof. Ron Wakai (UW), and Prof. Janette Strasburger (MCW)**

**INVITATION/SUMMARY**

**You are invited to take part in a research study about the use of a new magnetometer to study magnetic fields produced by the heart. We are testing the usefulness of this device for measuring the magnetic fields produced by the hearts of unborn babies. Your participation is voluntary. Approximately 20 subjects will participate in this study at the University of Wisconsin-Madison.**

**WHAT IS THE PURPOSE OF THE STUDY?**

The purpose of this study is to assess the new magnetometer's performance in measuring the magnetic fields produced by the hearts of unborn babies.

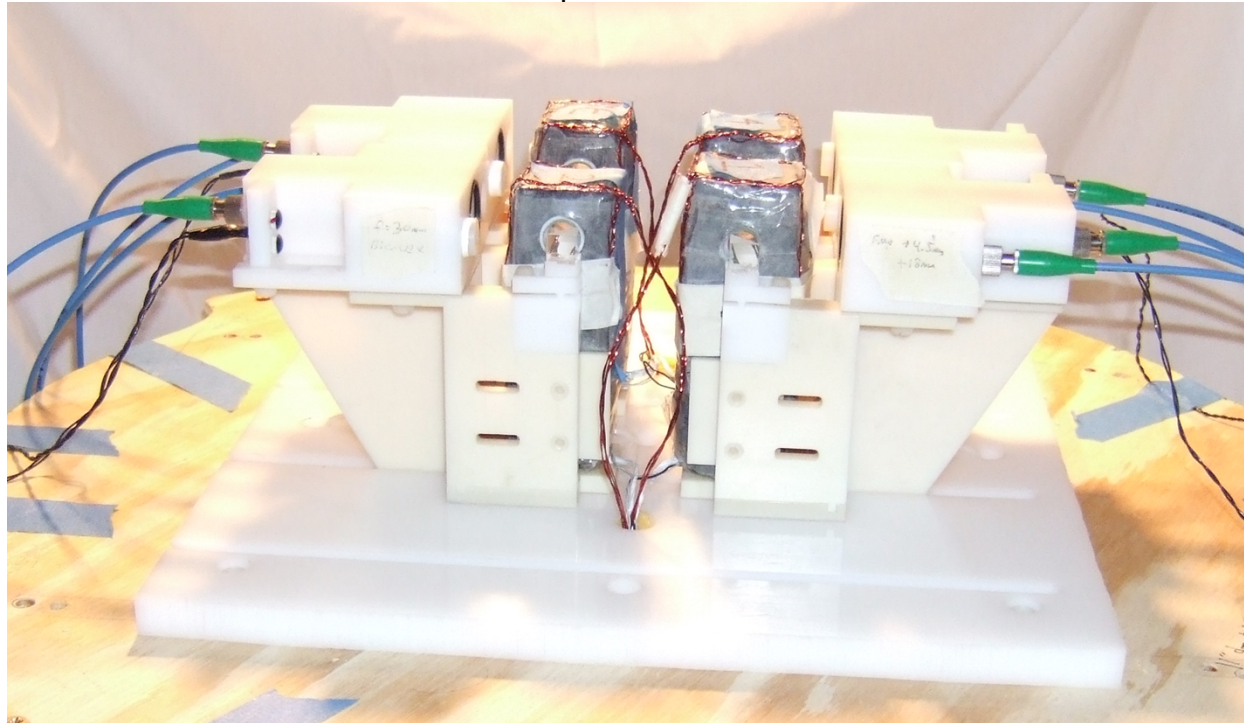
The magnetometer is an approximately 1ft by 1ft square piece of plastic on which a small oven and some optical and electronic devices are mounted. The magnetometer is warm to the touch but not uncomfortably so. The magnetometer is investigational, which means that the FDA has not cleared it for clinical use and it can only be used for research purposes.

Similar magnetometers have been used for many years to measure such things as the magnetic fields of the earth and planets. Other magnetometers, called SQUIDS, have been used previously for detecting the very small magnetic fields produced by humans. SQUIDS are a costly technology, however, and this new atomic magnetometer has the promise of being able to measure human magnetic fields at much lower cost. A photograph of the device is shown at the top of the next page.

**WHAT WILL MY PARTICIPATION INVOLVE?**

If you decide to participate in this research study, you will be asked to come to the Biomagnetism Lab for 3 study visits, each 1-2 hours long, approximately once every two weeks. You will be asked to wear special non-magnetic clothing similar to a hospital gown, and remove jewelry and other metallic items. You will enter a specially constructed room located at the UW Biomagnetism Laboratory that removes external magnetic fields in order to make it easier to see the fields produced by your body. Once in the room, you will sit in a chair or lie on a table. An ultrasound will be taken to locate the position of your baby. His or her magnetic fields may first be measured by a commercial SQUID instrument that is used for similar purposes. After completing this, the investigational instrument will be placed near you and you be asked to remain as still as possible for a few minutes at a time while measurements are being made. After

each measurement is made, you will be free to relax. When each session is done, you will be asked for feedback about the experience.



We wish to emphasize to you that this device is completely passive. It does not itself produce any magnetic fields or electric fields; it simply measures the fields that are naturally produced by your baby's heart. If you touch the device, no harm will come to you or to it. The position of the device is adjustable, but once in place it does not move.

During and after your sessions, UW and Medical College of Wisconsin researchers will evaluate the performance of the device based on the data acquired during your sessions.

Your participation in this research study is voluntary. If you decide not to participate, any relationship you have with the University of Wisconsin-Madison (UW-Madison), the University of Wisconsin Hospitals and Clinics (UWHC), or the Medical College of Wisconsin will not be affected in any way.

### **ARE THERE ANY RISKS?**

There may be some stray laser light in the room that comes from lasers contained inside the magnetometer. You will be given eye protection to render this completely safe. The magnetometer contains a hot oven but an insulating board will shield you from it. The board will feel warm to you.

The investigational instrument is not FDA approved but it is believed to present minimal risk to you.

The information collected from you during your participation will not be labeled with your name. The only information associated with the data is the gestational age of your baby. No other personal health information will be used in the study.

### **ARE THERE ANY BENEFITS?**

You are not expected to benefit directly from participating in this study. Your participation in this research study may benefit other people in the future by helping us learn more about detecting the magnetic fields produced by the heart.

### **ARE THERE ANY ALTERNATIVES?**

This is not a treatment study. The data collected will not be shared with you or your doctor.

### **WILL I BE PAID FOR MY PARTICIPATING IN THE STUDY?**

You will be paid \$20/hour for participating in the study.

### **IF I DECIDE TO START THE STUDY, CAN I CHANGE MY MIND?**

Your decision to take part in this study is voluntary. You do not have to sign this form and you may refuse to do so. You may completely withdraw from the study at any time.

**IF YOU DECIDE NOT TO PARTICIPATE IN THIS STUDY OR IF YOU STOP WHILE THE STUDY IS UNDERWAY, THE HEALTH CARE YOU RECEIVE FROM THE UW-MADISON AND ITS AFFILIATES WILL NOT BE AFFECTED IN ANY WAY.**

### **WILL THERE BE COMPENSATION FOR INJURY?**

In the event that you are physically injured as a result of participating in this research, emergency care will be available. You will, however, be responsible for the charges for the emergency care. There is no commitment to provide any compensation for research-related injury. You should realize, however, that you have not released this institution from liability for negligence. Please contact the principal investigator, Prof. Thad Walker, at 608-262-4093, if you are injured or for further information.

### **WILL MY CONFIDENTIALITY BE PROTECTED?**

Researchers might use information learned from this study in scientific journal articles or in presentations. None of this information will identify you personally. Only group characteristics will be published. The US Food and Drug Administration and other

federal agencies such as the National Institutes of Health may look at study records. Your contact information will be **protected by** storage on a secure computer.

A description of this clinical trial will be available on <http://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.

### **WHAT IF I HAVE QUESTIONS?**

If you have questions about this research, please contact the study investigator, Prof. Thad Walker, at 608-262-4093. If you have any questions about your rights as a research subject or complaints about the research study that you could not resolve with the study team contact UWHC Patient Relations Representative at 608-263-8009 or the University of Wisconsin Medical Foundation Patient Relations Representative at 800-552-4255 or 608-821-4819.

### **Authorization to participate in the research study:**

**I have read the information in this consent form, reviewed any questions, and I voluntarily agree to participate in this study. I have received a copy of this consent form.**

\_\_\_\_\_  
**Signature of Subject**

\_\_\_\_\_  
**Date**

\_\_\_\_\_  
**Signature of Person Obtaining Consent**

\_\_\_\_\_  
**Date**