

**NEIRB**  
New England Institutional  
Review Board

August 29, 2011

Irving Weinberg, MD, PhD  
Applied Pulse Power, Inc.  
2025 Dryden Road  
Freeville, NY 13068

Re: **NEIRB# 11-153**: WMP 5 "Sensory Effects of Rapidly-Changing Magnetic Fields" and  
Amendment I dated August 19, 2011

Amendment Approval Date: August 29, 2011

Dear Dr. Weinberg:

This is to inform you that New England Institutional Review Board (NEIRB), Thursday Board (formerly Board A) has reviewed **Amendment #1 dated August 19, 2011** for the above-captioned study. The changes to the study have been approved.


Please find the revised Informed Consent document, NEIRB version 2.0 enclosed. You will note that the date at the bottom right hand corner indicates an updated approval date of 8/29/2011. Only NEIRB-approved informed consent documents should be used. It must be signed by each subject who will participate in this study prior to the initiation of any protocol procedures. In addition, each subject must be given a copy of the signed consent form.

- All active subjects are required to be re-consented.

The approval period for the study ends on 5/18/2012. Any additional modifications in the research protocol, study site/ personnel, or consent form during this time period must first be reviewed and approved by NEIRB.

Please feel free to call me if you have any questions.

Sincerely,

  
Michelle Ferretti, CIM  
Administrator

cc: NEIRB Chair



**INFORMED CONSENT TO TAKE PART IN A RESEARCH STUDY****TITLE OF STUDY: Sensory Effects of Rapidly-Changing Magnetic Fields****INVESTIGATOR: Irving Weinberg, MD, PhD  
301-346-7944 (24 Hours)****SPONSOR: Weinberg Medical Physics LLC**

You are being asked to take part in a research study evaluating the sensory threshold for changing magnetic fields. This study is being conducted for research purposes. It will take about an hour of your time. Taking part in the study is entirely voluntary. The nature of the study, the risks, inconveniences, discomforts, and other pertinent information about the study are explained below. A member of the study staff will read through the consent with you and discuss all the information. When you think you understand the study, you will then be asked if you agree to take part. If you agree, you will be asked to sign this consent form. Once you sign it, we will give you a signed and dated copy to keep.

You may show this consent form to family, other doctors, and friends before you sign it. You may want to discuss it with them to help you decide if you want to be part of the study. If you don't know another doctor, but want a second opinion about this study, please ask. The study doctor will give you the name of another doctor that you can talk to.

**Purpose:** This study is being conducted to improve magnetic resonance imaging (MRI) scans by reducing the time required for imaging. Experience has shown that unpleasant side-effects from magnetic pulses used in MRI (for example, tingling or tapping sensations) can be reduced when the magnetic pulses are shortened. In this study, we will explore whether this effect holds true when very short magnetic pulses are applied. In this study, 25 subjects will be examined, at this site only.

You will not be able to participate if you have a history of abnormal heart rhythms, an implanted pacemaker or defibrillator, metallic materials or visible tattoos on your right hand or wrist, if we cannot easily measure your pulse, if your heart rate is irregular or rapid, if your blood pressure is low, or if you are breathing fast.

**Procedures:** If you choose to participate in the study, you will be asked questions about any medical conditions you may have, and your height, weight, hand size, blood pressure and pulse rate will be recorded by a Study Coordinator who is not an employee of the Sponsor of the study. The distance between your wrist and the center of your chest will also be recorded. You will then be paid for participating in the study. You will be exposed to magnetic fields in a single session for a total time of about one hour. You should not eat or drink for two hours prior to the exposure to the magnetic fields. The Study Coordinator and a physician will be in the room with you at all times during the study.

You will be asked to wash and dry your hands. You will then be asked to insert your right arm within an insulating sleeve. The insulating sleeve is surrounded by a coil of insulated wires. The coil will be placed as far as possible from the center of your chest in order to reduce the magnetic field at your heart. The coil will be activated by electric currents from an amplifier in

order to generate high magnetic fields. The magnetic fields will last less than a second each time the coil is pulsed. Sometimes, however, no current will be applied to the coil. The operator will be aware of when these "sham" pulses are delivered, but you will not. The operator will always tell you that a pulse was delivered even though sometimes a current will not be applied. The pulsed magnetic fields (including the "sham" pulses) will be applied a total of thirty times. After each time the coil is pulsed you will be asked if you notice any sensation (for example, tingling or tapping). You may hear noises as the amplifier is turned on and off, but this does not count as a sensation to be recorded. You will be asked to rate the sensation from 0 to 4, where 0 means no sensation, 1 means barely-noticeable sensation, 2 means easily noticeable sensation, 3 means unpleasant sensation, and 4 means very unpleasant sensation. If you say that the sensation is very unpleasant, the study at that current level will be discontinued immediately. If you tell anybody in the room that you wish to stop the study at any time for any reason, your study will be stopped immediately. If you complain of, or you are observed to be in distress, the entire study will be stopped immediately, and you will be transported to a nearby medical facility for evaluation and treatment if necessary at no cost to you.

**Risks:** Pulsed magnetic fields can cause electric currents to stimulate the heart, which could potentially cause abnormal heart rhythms. The risks of abnormal heart rhythms are very low in this study, because even though the magnetic fields are very strong in the coil around your hand, they are very low near your heart. The risk of abnormal heart rhythms from this study is about the same as for any person undergoing a routine MRI examination. You may experience discomfort in your hand, which is what we are trying to measure in this study. There is no scientific evidence to suggest that the discomfort in your hand will continue after the study is over.

**Benefits:** You will not personally benefit from this study.

#### **What happens if you have a research related injury?**

If you suffer a physical injury as a result of your participation in this study, the Sponsor will pay for medical expenses to treat the injury. You may receive medical care in the same way as you would normally. If you complain of, or you are observed to be in distress during the study, the entire study will be stopped immediately, and you will be transported to a nearby medical facility for evaluation and treatment if necessary at no cost to you. No funds have been set aside for payments or other forms of compensation (such as for lost wages, lost time, or discomfort). However, you do not give up any of your legal rights by signing this consent form.

#### **Do you have to be in this study?**

Your participation in this study is voluntary. Your refusal to participate or your withdrawal from the study will involve no penalty or loss of benefits to which you are entitled. You may stop your participation at any time without affecting your ongoing medical care. If you choose to stop the study, the data collected up until the time you withdraw will still be used as part of the study.

#### **Can you be removed from the study without your permission?**

Your study doctor may end your participation in this study for any of the following reasons:

1. If you develop a side effect or medical condition that may place you at risk of further complications by continuing your participation
2. If you are unable to keep your scheduled appointments;
3. If the study is cancelled by the sponsor, the New England Institutional Review Board or by the FDA;
4. For administrative reasons.

**Alternatives:** As this is not a treatment study, your alternative is to not participate.

**Compensation:** You will be paid \$150 for your participation in this study.

**Investigator Financial Interest**

The Principal Investigator of the study, Dr. Weinberg, is also the owner of the sponsoring company.

**Confidentiality:** This form, which contains your name, will be kept in a locked file cabinet at the study site for one year, and will then be destroyed. Aside from the copy given to you at the time of the study, this form will not be copied or entered into a computer. At the time of the study, your case will be assigned a number which will be given to the study Sponsor, along with your responses about the magnetic fields recorded by the Study Coordinator. In this way, the study Sponsor will have no way of identifying your study results individually, unless you choose to contact the study Sponsor yourself and volunteer that information. No information by which you can be identified as a study participant will be published. Representatives of the Food and Drug Administration (FDA) or New England Institutional Review Board (NEIRB) may inspect and copy records.

**Who do you contact if you have questions about the study?**

If you have questions or concerns about the study, or if you experience a research-related injury, you can contact Dr. Weinberg at 301-346-7944.

If you have questions about your rights as a research subject, or other concerns about the research, you can contact the New England Institutional Review Board (NEIRB) at 1-800-232-9570.

**VOLUNTEER'S STATEMENT:**

I have been given a chance to ask questions about this research study. These questions have been answered to my satisfaction. I may contact Dr. Weinberg if I have any more questions about taking part in this study. Dr. Weinberg is being paid by the sponsor for my participation in this study.

I understand that my participation in this research project is voluntary. I know that I may quit the study at any time without harming my future medical care or losing any benefits to which I might be entitled. I also understand that the investigator in charge of this study may decide at any time that I should no longer participate in this study.

If I have any questions about my rights as a research subject in this study I may contact:

New England Institutional Review Board  
Telephone: 1-800-232-9570

By signing this form, I have not waived any of my legal rights.

I have read and understand the above information. I agree to participate in this study. I understand that I will be given a copy of this signed and dated form for my own records.

\_\_\_\_\_  
Study Participant (signature)

\_\_\_\_\_  
Date

\_\_\_\_\_  
Print Participant's Name

\_\_\_\_\_  
Study Coordinator (signature)      Date

\_\_\_\_\_

\_\_\_\_\_  
Study Coordinator's Name

\_\_\_\_\_  
Date