

# **Consent by Normal Subject for Participation in Research Protocol**

## **Magnetic Resonance Imaging and Spectroscopy at 4T**

### **Sample Consent Form**

You are invited to participate in a magnetic resonance imaging (MRI)/ Spectroscopy study in an investigational device which operates at high magnetic field strength. MRI produces images or spectra (signals from the chemicals in your body) through excitation of nuclei in atoms by radio frequency waves when placed in a magnetic field. The magnetic field strength of this device has FDA approval, however, the long term risks are as yet unknown there could be adverse effects that are delayed or very mild, such that they have not yet been recognized. We hope that this machine will enable us to improve our diagnostic capabilities. You are selected to participate because of the region to be studied and the indication of your examination.

If you decide to participate, you will be placed in a large magnet. Most people experience no ill effects from the large magnetic field, but some people do report dizziness, mild nausea, headaches, a metallic taste in their mouths, or sensation of flashing lights. These symptoms, if present, subside shortly after leaving the magnet. No serious ill effects have been reported to date at any site operating at this magnetic field strength. The length of the entire study should be less than 1.5 hours.

A similar study could be performed on our standard MRI scanners. However, we expect the higher magnetic field strength which is utilized in the proposed study will improve our resolution and, hopefully, diagnostic capabilities. This study will not be performed in lieu of MRI in an FDA approved scanner.

Any information obtained in connection with this study that can be identified with you will remain confidential and will be disclosed only with your permission. In any written reports or publications, no one will be identified or identifiable and only aggregate data will be present.

In the event that this research activity results in an injury, treatment will be available at the University of Minnesota Hospital and Clinics, including first aid, emergency treatment and follow-up care as needed. Payment for any such treatment must be provided by your or your third party payer, if any (such as health insurance, Medicare).

Your decision whether or not to participate will not affect your future relations with the University of Minnesota Hospital in any way. If you decide to participate, you are free to discontinue participation at any time without affecting such relationships.

If you have any questions about the research and/or research subject's rights to report a research related injury, please call Dr. Charles Truit at (612) 626-2365.

If you have any questions or concerns regarding the study and would like to talk to someone other than the researcher(s), contact Hospital Patient Relations, 2-499 University Hospital, 500 Harvard Street Southeast, Minneapolis, Minnesota 55455; telephone (612) 626-5654.

You will be offered a copy of this form to keep.

You are making a decision whether or not to participate. Your signature indicates that you have read the information provided above and have decided to participate. You may withdraw at any time without prejudice after signing this form should you choose to discontinue participation in this study.