

## Language for IRB Human Subject Protocols & Consent Forms for Human MR Research Studies at the Lucas Center

*The following information enclosed in quotation marks concerning MR scans is for inclusion in human subject protocols and consent forms for 3T2, 3T3, 3T1 PET-MR and 7T human research studies conducted at the Lucas Center.*

### **Study Location**

"Stanford University"

### **Investigational device?**

"Yes" and "Non-significant Risk"

### **IDE Exempt device?**

"Yes"

#### **What is an Investigational Device Exemption (IDE)?**

An IDE is issued by the FDA to allow the use of investigational devices in human subjects.

The IDE permits use of the device in a clinical investigation to evaluate the safety and/or efficacy of the investigational medical device.

An IDE may be held either by a commercial sponsor or by a physician-investigator.

Clinical studies of SR investigational devices must comply with FDA's investigational device exemption (IDE) regulations and be conducted only with IRB approval.

More information is available at this site: .

If an investigational device is a "non-significant risk device", an investigator does not need to submit an IDE; the IDE will be "considered approved" under FDA regulations.

Such devices do not have to comply with FDA premarket approval and performance standards prior to use in research studies.

Such studies of devices "considered approved" by the FDA must still be submitted to the IRB for approval prior to use in human subject research.

All equipment at the Lucas Center is kept in a locked facility and access is granted by Anne Sawyer, Magnet Manger (amsawye@stanford.edu, 650.302.2846).

"Some of the RF coils, imaging accessories and equipment, and imaging software used to scan subjects at the Lucas Center are not FDA-approved."

"The MR research being conducted requires highly specialized equipment and imaging software that does not exist in the clinical MR market so it is designed and manufactured by researchers at the Lucas Center and other hardware companies. Although some of the imaging software and equipment are not FDA approved, they have been tested for safety and are very similar to what is used regularly in clinical MR examinations. The MR personnel are highly trained in the set-up, utilization, and monitoring of this equipment."

### **Medical equipment used for humans also used on animals?**

"Yes"

### **Use of Patient-Related Equipment (also used on animals)**

(Describe disinfection procedures)

"The bed/table and accessories that are used for the animals is different than the table humans use. Physiologic monitoring equipment is cleaned with a commercial disinfectant such as Roccal, Conflick, Sani-Wipes, or a 10% Bleach solution. All RF coils and positioning accessories are wrapped in plastic wrap or plastic bags for use with animals. Everything, even if it is animal use only, is cleaned with the above disinfectants after every use even if they are wrapped in plastic. The Lucas Center is checked yearly by several groups at Stanford who approve animal research in human systems: Stanford Health & Safety. We are reviewed by: Stanford APLAC panel; USDA; NIH; and Aalac."

## **Terminology**

### **Please do not use the word "radiowaves"**

Please use the phrase "radiofrequency magnetic field(s)" instead of radiowaves

## **Safe storage of personal items**

"A locker will be provided for you to secure all your items and valuables."

## **Use of video and taping devices**

"While performing tasks during the MRI, we may video record to monitor your behavioral responses."

## **Risks**

### ***Prototype or non-FDA-approved equipment***

"Some of the radiofrequency imaging coils, imaging software, and other devices being used to conduct scans at the Lucas Center are not approved by the FDA."

### ***Metallic objects and projectiles***

"As metallic objects may experience a strong attraction to the magnet, it is very important that you notify the researcher of any metal objects, devices or implants that are in or on your body before entering the magnet room. This includes biomedical devices such as pacemakers and aneurysm clips, prostheses, and any other metallic objects embedded in the body such as bullets, buckshot, shrapnel, and any metal fragments from working around metal."

"All other metallic objects must also be removed from your person prior to entering the magnet room or approaching the magnet to prevent them from becoming a projectile or being pulled by the magnet. This includes keys, jewelry, body piercing, pocket knives, money clips, paper clips, safety pins, hair pins, and barrettes. In addition, objects such as watches, credit cards, and hearing aids could be damaged in the presence of the magnetic field."

### ***Risk of heating during the scanning***

"There is a risk of heating from radiofrequency imaging coils and their cables, button response boxes and their cables, and the cables from monitoring devices that record physiologic processes such as heart beats per minute or electrical activity of the brain. Please report any heating sensation immediately. You may have the scan stopped at any time if this occurs."

### ***Tattoos including permanent eye makeup (tattooed eyeliner & eyebrows)***

There is a small risk that areas with tattoo(s) could become warm, irritated and painful, and remain so for several days due to exposure to the RF electromagnetic field.

If permanent eye makeup (tattooed eyeliner and/or eyebrows) is present, please contact the MR safety officer at the MR facility to obtain approval to scan.

### ***Peripheral nerve stimulation (1.5T and 3.0T)***

"There is a possibility that you will experience a localized twitching sensation due to the magnetic field changes during the scan. This is not unexpected and should not be painful. However, you may have the scan stopped at any time if this occurs."

## **Pregnancy**

"If you are or are trying to get pregnant, the effects of the scan on a fetus are unknown and, therefore, we will not perform the examination at this time."

### ***Dizziness & Nausea***

"Dizziness and nausea may occur if the head is moved rapidly within the bore of the magnet."

### ***For scanning done using the Eye Tracker, please include:***

The IR source(s) are infrared-emitting diodes, similar to common light-emitting diodes (LEDs). The total amount of infrared light falling on the subject's eye is acceptable by the Occupational Safety and Health Administration."

### ***For scanning done using the EEG, please include:***

You may be fitted with a cap having wires attached for the purpose of recording electrical activity from your brain (an electroencephalogram). The connections may cause some temporary discomfort from the pressure of lying on them however, there is no known danger associated with the procedure.

### **Incidental findings**

For those of you who are scanning normal volunteers, controls or who do not have your subject's images formally interpreted by a radiologist, it is recommended to include the following in your consent form:

"Incidental Findings: The investigators for this project are not trained to perform radiological diagnosis, and the scans performed in this study are not optimized to find abnormalities. The investigators and Stanford are not responsible for failure to find existing abnormalities in your MRI scans. However, on occasion the investigator may notice a finding on a MRI scan that seems abnormal. When this occurs, a radiologist will be consulted as to whether the finding merits further investigation, in which case the principal investigator of the research study being conducted will contact you and your primary care physician and inform you of the finding. The decision as to whether to proceed with further examination or treatment lies solely with you and your physician. The investigators, the consulting radiologist, and Stanford are not responsible for any examination or treatment that you undertake based upon these findings. Because the images collected in this study do not comprise a proper clinical MRI series, these images will not be made available for diagnostic purposes – **unless the patient information is entered in RIS and the images sent to PACS; then the scan subject may go to the Department of Radiology at Stanford Hospital and request a report and a CD of the images.**"

In the event that a potential abnormality on the MR images is detected by the researchers, Anne Sawyer, Lucas magnet manager, is to be notified immediately to report the potential issue. Films of images are not be provided to the researcher or volunteer scan subject as the images were obtained using a research MR scan protocol and not from a clinically-ordered MR scan protocol prescribed by a radiologist at Stanford.

## **IV Contrast Media**

### **Intravenous Contrast Enhancement**

MRI images collected following injection of a contrast agent may be more useful for finding breast disease than MRI without this drug.

MRI is an imaging technique that produces images of the body that are shown as slices of the whole body.

The brightness of parts of the body in the MR image can be changed by injecting these chemicals, called contrast agents.

This may increase the possibility of detecting some kinds of breast nodules or diseases.

Some patients develop a slight headache or nausea from the agent.

Other risks include pain, bruising, infection and extravasation.

Since your kidneys remove the agent from your body, if your kidneys do not function well you should not receive the contrast agent.

If you have a history of poor kidney function please notify the operator/investigator.

If you have had a previous reaction to Gadolinium-based contrast agents or a history of severe allergies, please notify the operator/investigator.

### **Additional Information**

#### ***No Sedation at Lucas***

No sedation, conscious sedation or sedatives can be administered at the Lucas Center.

This includes oral, IV (intravascular), IM (intramuscular), Chloral Hydrate, Valium,

Versed, etc. unless pre-approved by the Lucas Center Safety Committee (Bob Herfkens,

Anne Sawyer, and Gary Glover) and an anesthesiologist is present for the entire examination.

#### ***Devices or Administration of Contrast Media or Gas:***

If a device or administration of a contrast media or gas is being used as part of a research study, then it is to be included in the human subjects protocol and consent form as well as any potential risks associated with it.

#### ***A good phrase to include in all consent forms:***

"All forms of medical diagnosis and treatment -- whether routine or experimental -- involve some risk of injury."

#### ***English as a second language***

If a research subject is not fluent in English, i.e., read, write, and understand, the

consent must be written in the subject's language per Dr. David Oakes, IRB Panel Chair.

Translation services can provide assistance.