

2019_0121 Standard Operating Procedure
New Lucas MR Research Study with MR Technologist

A. Contacts

- I. Karla Epperson, Magnet Manager
karlae@stanford.edu, 650-521-7836
Contact for MR studies (human, animal model or phantom)
- II. Yamil Saenz, Veterinarian
ysaenz@stanford.edu, 408-813-1640
Contact for animal model studies
- III. Jane Nguyen, Service Center Manager (Contact for financial information)
janenz@stanford.edu, 650-736-7928

B. Support documents and information (Human Research Studies) provided by **Karla**

- I. Language for Human Subjects Protocols and Consent Forms
- II. Template for Human Subjects Protocols
- III. Template for Consent Forms
- IV. Lucas User Contract Form
- V. Maps and directions to the Lucas Center
- VI. Cell phone numbers for **Karla** and MR Research Technologists
Karla Epperson 650-521-7836, Kevin Epperson 650-387-0194
(Clinical coordinators give all cell phone numbers to scan subjects)

C. MR studies (Human)

- I. Submit documentation to **Karla**:
 - a. Lucas User Contract Form
 - b. IRB-approved Human Subjects Protocol
 - c. IRB-approved Consent Form
 - d. IRB approval
 - e. MR scan protocol (set of scan parameters)
 1. From Clinical Research Organization or other
 2. From Radiologist
- II. Use of MR contrast media for MR research study
 - a. Communicate type of contrast to be used to **Karla**
 - b. Communicate if contrast provided by study or purchased from Lucas
 - c. M.D. is required to be in Lucas Center for administration of contrast media
 - d. Healthcare professional to place IV (Technologist, nurse or MD) and second individual present to assist in the event of syncope (fainting) or temporary loss of consciousness
- III. Images to be sent to Stanford PACS (Please contact **Karla** for additional information)
 - a. No image interpretation required by Radiologist
 - b. Image interpretation required by Radiologist
 1. Collaboration with Radiologist
 2. Paid by research study
- IV. Transfer of images and data to Clinical Research Coordinator
 - a. Please contact **Karla** for information regarding the use of Flywheel

V. Condition of scan subject population

- a. Communicate to **Karla** any special scan subject conditions
 1. Quadriplegic, paraplegic or any ambulatory issues
 2. Seizures, asthma or psychiatric conditions
 3. Post surgery or biopsy
 4. Any painful or age-related conditions
 5. Height and weight as related to fitting into MR scanner
- b. Sedatives and conscious sedation use not allowed for Lucas MR scans unless:
 1. board certified anesthesiologist in attendance for entire exam and
 2. physiologic monitoring used.

D. MR Safety Screening

- I. Telephone or in-person screening conducted by the Clinical Coordinator prior to day of exam (Biomedical devices, implants and other conditions may require investigation by **Karla**)
- II. Communicate all as early as possible to **Karla** all concerns to obtain approval to scan at Lucas:
 - a. biomedical devices, implants, prostheses and acupuncture
 - b. prior surgeries
 - c. shrapnel or bullet fragments
 - d. metal fragments from injuries or accidents
 - e. tattoos
 - f. body piercings (all must be removed prior to MR scan)
 - g. wigs, toupees or hair extensions
 - h. allergies (if a MR contrast media are being administered)
 - i. asthma (if gases are being administered)
- III. Following information submitted to **Karla** for all concerns:
 - a. Date of injury, accident or surgery
 - b. Country in which surgery was conducted
 - c. Biomedical devices and implants
 1. Reason for implantation or presence on body
 2. Name or model number of the device
 3. Name of manufacturer of the device
 4. Material from which the device is made
 5. Location in or on body
 6. Copy of patient device information card if present

E. Informed Consent

- I. Form completed by scan subject
 - a. Before the day of the scan (or)
 - b. On the day of the scan before the MR examination
- II. Consent form must be in a language that the scan subject can read (No translations allowed - Stanford policy)
- III. Copy of consent form is given to scan subject by the Clinical Coordinator (Stanford policy)
 - a. Scan subject should be encouraged to keep consent form with their medical records
 - b. Consent forms include the name and phone number of the Principal Investigator (PI) and the IRB office

F. Lucas Center Secure Subject Database (ssdb)

- I. Clinical coordinator(s) obtain login and password from **Karla** to input scan subject information to initiate scheduling processes
- II. If a specific Lucas MR scanner is being used for the study, that is included in the Visit Description in the ssdb entry as well as **visit or week number specific by the research study**
- III. After input of scan subject information by Clinical Coordinator in ssdb, an automatic confirmation email is sent to Clinical Coordinator that includes link to scan subject information in ssdb database
- IV. Scheduling of scan subject's MR examination is done via telephone and email; emails including link to scan subject information in ssdb and initials in Subject heading
- V. Rescheduling that occurs in the event of a cancelation will use same ssdb entry of scan subject information; an email is resent with link to scan subject information in ssdb and initials in Subject heading

G. MRI scan time appointments

- I. Scan subjects will be provided with one time, the 'Arrival Time' at the Lucas Center.
- II. Arrival times are scheduled between the hours of 7:30 am and 3:00 pm; if arrival times are needed outside of these hours, please contact **Karla** to discuss.
- III. Clinical coordinator gives **all cell phone numbers to scan subjects (see section B, VI)**

H. Cancellation of scheduled MR scan subject appointments by the Clinical Coordinator

- I. Email is sent to **Karla** (including ssdb link if possible)
- II. If less than 24 hours, in addition to email, calls are made to cell phone of **Karla** or MR Research Technologists in order to cancel MR scan time with adequate notice so other researchers may use the MR scanner time

I. Scan subject preparation

- I. No large meals nor coffee or tea in the hour before arriving for their MR scan appointment
- II. Brain scans: no facial or eye makeup present on the scan subject; no wet hair, hair products or extensions (wigs and toupees will be removed for the MR examination)
- III. Body scans: no lotions or deodorant present on the body
- IV. **No** underpants or shorts with metal snaps, threads or antimicrobial material (exercise clothes)
- V. If possible, the scan subject should leave jewelry, piercings and hair accessories at home

J. Day of the MR scan appointment

- I. If possible, clinical coordinator meets scan subject at the Lucas Center at confirmed arrival time
- II. Obtain parking slip from MR Research Technologist
- III. Lucas screening form completed and reviewed by MR Research Technologist; MR screening form is completed for each and every MR examination conducted at the Lucas Center
- IV. Scan subject will change out of street clothing into disposable scrubs and foot covers provided by the Lucas Center
- V. Scan subject's clothing and personal items will be secured in a locker in the MR suite
- VI. Scan subject required to wear hearing protection including earplugs or earplugs and earmuffs
- VII. Post MR scan, subject will complete Lucas Center Exit Form
- VIII. MR Research Technologist archive data to two CDs (one for PI and one for Clinical Research Organization (CRO))

K. Incidental Findings

- I. Study images that do not normally go to PACS as part of a collaborative Radiology study
 - a. Potential abnormality seen on images is reported to **Karla** or MR Research Technologists
 - b. Accession number (and medical record number if necessary) is generated
 - c. Image annotation is modified by MR Research Technologists and images are sent to PACS
 - d. MR Research Technologist notifies Radiologist via email to obtain image interpretation
 - e. Image interpretation is communicated to Principal Investigator (PI)
 - d. Radiologist may provide consultation to PI regarding outcome of image interpretation
- II. Please do not push images to PACS without appropriate information including accession

L. Images requested by scan subjects

- I. Images that go to PACS and receive an interpretation by a Radiologist (either Incidental Findings or Study is conducted in collaboration with Radiologist and normally are sent to PACS for image interpretation)
 - a. Scan subject may go to film library in Radiology Dept of Stanford Hospital to receive a copy of the report and their images
- II. Images that are not normally sent to PACS as part of the study
 - a. Images are not to be given to the scan subject, scan subject's family or physician (except for souvenir copy from printer in magnet suite); this is a Stanford University policy