Lucas MR Service Center
Phase N: Expanded Human Subjects Scanning

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Department of Radiology
Recent History: MRI Scanning @ Lucas

• Last User scan 3T3  Mar. 15
• Scanning Phantoms June
• Scanning Own-Lab members
• Scanning Large animals  July
• Scanning Patients benefited by research studies
• Scanning Stanford affiliates
Today: Expanded HS Research

- On Oct. 21 the DOR issued new guidelines on expanded HS research: https://cardinalrecovery.stanford.edu/research/research-recovery/

RESEARCH WITH COMMUNITY PARTICIPANTS THAT ARE LOW RISK (I.E., WHO ARE NOT MEMBERS OF GROUPS THAT ARE PARTICULARLY VULNERABLE TO COVID-19).

The following set of characteristics describe individuals who are particularly vulnerable to COVID-19, and who therefore are not allowed to participate in in-person human subjects research on campus at this time:

a. Individuals over the age of 65,

b. Any individual with an underlying medical condition for which the CDC says they are at increased risk of severe illness from COVID-19 (see People with Certain Medical Conditions), unless the individual is participating in a clinical trial or clinical research investigating their medical condition. As of October 20, this list includes: Cancer, Chronic kidney disease, COPD, Heart conditions, Immunocompromised state, Obesity, Severe Obesity, Sickle cell disease, Smoking, and Type 2 diabetes mellitus.

On October 21, IRB-approved clinical and non-clinical longitudinal and cross-sectional in-person human subjects research on campus with community participants that are low risk (i.e., who are not members of groups that are particularly vulnerable to COVID-19, see above) will be allowed to resume if they meet the following requirements:
1. Prior to restart, PIs must prepare SoPs that detail how study protocols will meet each of the requirements below. These SoPs must: (a) incorporate lab SoPs and requirements; (b) incorporate local unit and building SoPs; (c) be in compliance with all EH&S requirements; and (d) be approved by the local unit leadership, Chair and/or Institute Director, Dean/School. If researchers must change protocols to accommodate health and safety guidelines, they will need to submit these protocol revisions to their human subjects research institutional review boards (https://researchcompliance.stanford.edu/panels/hs).

2. Researchers must use a calendar (including who, where and when) to record research sessions and maintain a record of participants’ contact information for contact tracing. To maintain participant confidentiality, researchers must protect these data and ensure limited access to this information. Researchers who have access must be able to provide participant contact information in case it is needed for contact tracing.

3. Prior to the scheduled research session, researchers will send materials describing the research process, required face coverings and PPE, physical distancing and density requirements, and COVID-19 symptom check to participants before they arrive on campus.

4. Prior to the research session, researchers will send a letter (see template) on Stanford letterhead to participants stating that the participants have permission to enter the zone of the research facility and may only visit the approved zone. Researchers will let participants know that they must bring the letter with them when they come to campus for the research session.

5. On the same day of the session, prior to arriving on campus, researchers will call participants and assess whether they have COVID-19 related symptoms. Only participants who do not report COVID-19 related symptoms will be allowed to...
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6. If participants are coming from off-campus, researchers will meet participants when they arrive on campus, at an assigned outdoor space (e.g., parking lot) prior to building entry. Researchers meeting participants will wear appropriate face coverings and PPE and maintain the minimum of 6 feet physical distance between the researcher and the research participant. Researchers will provide face coverings and any additional PPE as needed to participants, who will put them on immediately upon meeting the researcher.

7. Researchers will ensure that they and the research participants will wear face coverings and any additional PPE required before entering the building and during the research session.

8. Researchers and participants will sanitize their hands upon building entry. Researchers will provide the hand sanitizer.

9. Researchers and participants must adhere to current physical distancing and density requirements throughout the research session.

10. Prior to restart, researchers must place floor markings throughout the research area indicating to participants where they should stand and sit during the entire research session.

11. After the research session, researchers will escort participants back to their vehicles, or location where they met the participant, to ensure that participants leave campus immediately after their study participation. If participants are Stanford affiliates, researchers will escort participants out of the building immediately after the session.
Research Approval

• All PI’s must have approval from their department to restart scanning, but must also submit approved departmental SOP to radresearch.Stanford.edu

https://radresearch.stanford.edu/covid-19
Scanner Scheduling

- Usual scheduling system is in use with several specifics:
  1) (a) must check ‘have read Lucas SOP’
     (b) operator name is entered in comment field;

Note: Schedule program will change soon
Scanner Scheduling

- Usual scheduling system is in use
  1) (a) operator name is entered in comment field; (b) must check ‘have read Lucas SOP’
  2) 1/2 hour allotted between scan sessions, for disinfection, room air exchange
  3) Priorities will be accommodated to extent possible

- Usual scan rates apply; no charge for interstices
Stanford Training/ HealthCheck

- Stanford Hygiene course, HealthCheck mandatory for Stanford affiliates
Lucas Disinfection/Safety Training

• All operators will need Lucas mandatory training on how to perform disinfection of the scan facilities—scanner, control room, accessories.

• A technologist will meet *first-time-back* researchers at the scanner to provide guidance—Contact Karla to arrange a training session: karlae@stanford.edu
FAQ: Covid Testing for operators?

- Not currently mandated by Stanford…

- but Encouraged! Seems like a socially responsible thing to do.

Operators listed in ORMS at 20% time on campus (1 day/week) are eligible for free testing (pick up test kit, perform nasal swab, return, results in 1-2 days)
Masks

Many masks have small metal tab to conform mask to face.
- Safety concern (attractive forces, RF heating
- Will destroy T2*-weighted imaging on a participant
Scanning Procedures: All scanners

• Lobby (3T2, 3T3) or other ingress point:
  - if (Stanford_affiliate)
    Check-in procedures- QR codes for HealthCheck & bldg. login;
  else
    Visitor Permission Form
    Visitor check in- Redcap computer for COVID screening/attestation
  end
  - Face masks
  - Distancing, density, hand hygiene

• Control room:
  - Wipe counters, computers, etc. before use.

• Scanner room/ rest of suite:
  - Disinfect anything touched before/after use. Cover coils, phantoms.

• Session Conclusion: Disinfect. Secure data if necessary. No processing may be done at Lucas. Maintain masks until leaving building.
Participant Check in

Subject Demography Form

Please complete the survey below.

Thank you!

COVID-19 Screening, Mitigation, and Assumption of Risks

This document includes COVID-19 screening questions and must be completed by all visitors for imaging (Lucas). In addition, this form explains what steps are being taken to mitigate transmission. While these precautions are deemed to significantly reduce the risk of infection, it is important to recognize that by increasing their contact with other individuals and physical locations, infection does increase.

It is important that you disclose to Lucas any indication of having been exposed to COVID-19, experienced any signs or symptoms associated with COVID-19 disease as detailed below:

Lucas has implemented standard operating procedures to be followed by all researchers. These procedures are consistent with infection control guidelines from the Center for Disease Control (CDC), Occupational Safety and Health Administration (OSHA) and have been reviewed by Stanford Health and the Office of the Vice Provost and Dean of Research. The Lucas Center’s COVID-19 policy includes the following components:

1. Social Distancing/Density: At all times, researchers and visitors shall practice social distancing not in their household (> 6 feet of separation). The Lucas Center will adhere to University guidelines regarding number of people allowed in building spaces. Only the minimum number necessary to perform the study are allowed. In situations requiring transient, closer proximity, mask, face shields and gloves will be employed over the mask to reduce potential respiratory transmission
2. Face Coverings: All researchers and visitors are required to wear masks on entry to the building (campus building), which must be worn at all times. Masks of operators and scan with scan subjects are required to be worn and replaced if necessary. Masks MUST be worn by scan subjects during the scan. Masks are required to be worn by all personnel to reduce potential for disease transmission in the confined spaces of the magnet, coils, etc.
3. Hand Sanitation: Researchers and visitors are encouraged to practice good hygiene by washing hands with soap and water and/or using the available hand sanitizer and to not touch the face

Redcap-generated record ID

Include Area Code

Female

Male
## Density limitations

<table>
<thead>
<tr>
<th>Room</th>
<th>Area, Sq. Ft.</th>
<th>Num persons allowed</th>
</tr>
</thead>
<tbody>
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<td><strong>3T1</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Magnet room</td>
<td>690</td>
<td>6</td>
</tr>
<tr>
<td>Control room</td>
<td>196</td>
<td>2</td>
</tr>
<tr>
<td>Prep area</td>
<td>210</td>
<td>2</td>
</tr>
<tr>
<td>HyperPol. prep</td>
<td>160</td>
<td>2</td>
</tr>
<tr>
<td><strong>3T2</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Magnet room</td>
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<td>4</td>
</tr>
<tr>
<td>Control room</td>
<td>140</td>
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</tr>
<tr>
<td>Prep area</td>
<td>70</td>
<td>1</td>
</tr>
<tr>
<td><strong>3T3</strong></td>
<td></td>
<td></td>
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<tr>
<td>Magnet room</td>
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<td>5</td>
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<tr>
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<td>7</td>
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<tr>
<td><strong>0T1 (Mock scanner)</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Room</td>
<td>144</td>
<td>2</td>
</tr>
</tbody>
</table>
Mock Scanner

• Yes! Sign up as usual.

• Limited Size (144 ft$^2$):
  - 1 operator only, visitor may accompany but must sit outside room
  - Face shield must be worn by operator at all times.

• Disinfection procedures identical to scanners will be utilized.

Contact Karla for first-time-back training
<table>
<thead>
<tr>
<th>Room Code</th>
<th>Location</th>
<th>Size (ft²)</th>
<th>Limit</th>
</tr>
</thead>
<tbody>
<tr>
<td>P-069</td>
<td>basement, bottom of stairs</td>
<td>144</td>
<td>2</td>
</tr>
<tr>
<td>P-080</td>
<td>lightwell entrance, glass bridge</td>
<td>150</td>
<td>2</td>
</tr>
</tbody>
</table>

Contact Karla to sign up
Check list

1. Read Cardinal Recovery
   - Note limitations on COVID-vulnerable subjects
   - Prepare SOP, get approval from own dept., Radiology
   - Prep participant for COVID screening (letter, screening info, pre-scan call)
   - Modify IRB if needed

2. Read Lucas Human Subjects SOP
   - Arrange mandatory training with Karla
     (disinfection, subject check-in, density, landmarking)
   - Obtain PPE (MR-safe masks, face shields)
   - Follow changes to research- (density/distancing limits: e.g. 2 operators max)

https://med.stanford.edu/lucasmri/Lucas-phased-restart.html
Lucas Center Operating Procedures for Phased Restart

COVID-19 Updates for Research Scanning

Research MRI Scanning Phase 2:

Introduction

Stanford is cautiously restarting research in a phased approach, and has approved the scanning of phantoms and, beginning June 10 2020, a pilot study of human subjects under limited conditions, namely, the operator and participant must be members of the same lab. All users will have to have Stanford-mandated approval from their department, and are required to abide by Lucas Center policies provided here. Investigators must supply their own PPE, which includes masks, and for scanning humans, a face shield. As before the Center will supply gloves when scanning humans. Handwashing hygiene, social distancing and other regimens described in the documentation must be strictly adhered to in the Center. Safety of all persons is the topmost priority, which entails detailed attention to disinfection/cleaning.

Addendum: Starting July 15, 2020: You are allowed to scan Stanford affiliates (e.g. staff, trainees, faculty) who are approved to come to the main Stanford campus. Please see other details below and note the Lucas SOP below.

Before scheduling scans, the users must

1. Obtain approval for research restart from home department (Stanford-mandated);
2. Read and follow the Lucas Center SOPs;
3. Have Personal Protective Equipment.

The following are reference documents.

Standard Operating Procedures

- SOP: Scanning Phantoms (PDF)
- SOP: Scanning Humans (PDF)
- SOP: Animals (PDF)
- SOP: COVID Disinfection Procedure (PDF)
Principles

• Safety of all persons in the Lucas Center is paramount:
  -> Face masks, handwashing hygiene, social distancing and space
  -> Density limits must be maintained at all times.
  -> Important because wet and dry lab research is also performed in building.

We do not scoff at disinfection/PPE/physical distancing requirements or relax any limitations of operation that could affect safety. If you are cautioned by another that you missed a step, the only acceptable response is “Thank you”, and remediation.
Remote Scanning

- No longer supported. Scan users are not required to localize ACR phantom in head coil before leaving.
FAQ: Effect of wearing a mask on task fMRI

Wearing a mask may induce elevated ETCO2 and inspired [CO2], which may affect BOLD contrast.

Nasal cannula supplies medical-grade air to modulate ETCO2, while wearing mask or not, performing SM task during 9 min. scan.
Effect of wearing a mask on task fMRI

- 7.4% ETCO2 increase w/mask (capnography)
- no change in task activation
- baseline BOLD shift 42%
- FC in RS? (Xue Zhang)
Questions?

Lucas Service Center Executive Committee
  Tom Brosnan
  Karla Epperson
  Mehdi Khalighi
  Jane Nuygen
  Me

Mehdi Khalighi  Deputy director:
  Metabolic Imaging Center (3T1 PET-MRI),
  Lucas Service Center (3T2 & 3T3)

Brian Rutt (7T1)