

Rules for re-opening of human MR studies at the Zuckerman Mind Brain Behavior Institute

29 September 2020

Requirements for ZI staff

- Staff must be tested and must follow ZI rules for operation in the building.
- Staff must wear masks throughout experiments and interactions with subjects and other staff.

Requirements for subjects and external researchers

- All subjects and external researchers will be screened for COVID-19 symptoms and history by the study team the day before. There should be documentation of the screen results in the formal clinical or research records.
- All external researchers must use the ReopenCU app and do symptom attestation the day of the scan, and show the green pass to Security before entering JLGSC. If they have symptoms, they must send an alternate symptom-free colleague to scan or cancel the scan.
- On the day of the scan, subjects will be screened once more and follow ZI procedures for visitors entering the building.
- Subjects and external researchers are only admitted for studies if they meet health requirements and other restrictions to be determined.
- Contact information for subjects and external researchers must be stored securely and must be accessible for tracing subjects in case this becomes necessary to prevent the spread of the virus.

Procedure for interaction with subjects

- The subject is informed about the safety procedures by email before arriving.
- Subjects should arrive no more than 5 minutes before the appointment time, to avoid spending extra time in a waiting area.
- No one should accompany the subject unless they need assistance.
- A single researcher meets the subject in the JLGSC lobby.
- The researcher and participant must both wear PPE when in the building (face mask from first contact).
- The researcher is wearing a mask and hands a disposable mask and hand-sanitizer to the subject upon first physical contact in the lobby.
- The subject uses hand sanitizer immediately upon receiving it from the researcher.
- The researcher guides the subject to the elevator and to the scanner room, keeping at a 6-foot distance to other people throughout.
- The researcher may enter the elevator with the subject, but only when no third person is present in the elevator.
- Participants and staff are not required to wear gloves, but must wash hands before and after the scan.

- The number of people in the control room is limited to two (except when the subject is brought into the scanner room), or three when the nature of the study requires it.
- The number of staff interacting with the subject at close range is limited to one.

Personal protective equipment (PPE)

- Staff and subjects wear MRI-compatible masks throughout the interaction, from first physical contact between researcher and staff in the lobby to seeing the subject off in the lobby.
- The center must have a sufficient supply of disposable masks for staff and subjects in order to operate.
- If the experiment requires it, subjects may be instructed to move the mask down to their chins while in the scanner. However, they must replace the mask to cover mouth and nose before emerging from the scanner bore.

Post-study cleaning

- Any surfaces that came into contact with the subject including their bathroom, and/or their testing room if applicable, will be cleaned after they finish using them for each study. (Elevators are frequently cleaned by building staff.)
- Researchers are responsible for cleaning the facilities and equipment after each study as specified in the MRI Post-study Cleaning Checklist.

Study scheduling

- Studies will be scheduled with a margin of at least 30 minutes for cleaning and airing.

Contingency plan for unexpected incidents

- In case a subject or staff member shows symptoms that might constitute a risk of infection to other staff and subjects, the study is terminated, the subject sent home, the facilities cleaned.
- The incident will be discussed among the leadership to decide for how long to disallow subsequent studies.

Principal investigators are responsible for ensuring that the study and resuming it in the present period is approved by the responsible IRB.

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