

## **Brain Mapping Center COVID-19 Phase 2 Risk Mitigation Plans**

Frequent and rapid testing of staff and/or subjects to confirm that they do not have an active coronavirus infection is not available at this time. The current gold standard, currently being employed by UCLA Health to screen patients prior to medical procedures, is to obtain a nasopharyngeal swab for a PCR test with a typical turnaround time of multiple hours. Faster tests (5-15 minutes) exist, but currently have a high false negative rate and are not recommended by UCLA Health at this time. The swabbing procedure itself is unpleasant and the test identifies the individual's status at that point in time and does not reflect the infection status any time after.

Los Angeles County continues to confirm a significant number of new, community acquired COVID-19 cases daily, and we know that some individuals can be asymptomatic yet have the potential to transmit the virus to others. Consequently, absent effective rapid testing, we have to assume that everyone might be infectious. For research subjects, financial compensation for participation may serve as an incentive to conceal signs or symptoms of infection, justifying even more vigilance to guard against transmission from research subjects to other subjects or to staff.

Research imaging projects underway in the Brain Mapping Center address major health issues, and the Center is eager to facilitate re-initiation of research as quickly as risks can be appropriately managed. The definition of appropriate risk management will be guided by multiple sources including the IRB, medical school, campus, health system, and local and state public health authorities. The goal here is to summarize the unique safety issues with regard to research MRI scanning in the BMC and what risk mitigation strategies we can employ to move forward with scanning in a way that maintains risks at a level comparable to those currently encountered by research subjects and staff in their everyday life. These guidelines are intended to mitigate MR scanning risks in the BMC to the minimal risk level required to conduct human research with no direct benefit to the research participant as described for Phase 2 research in Appendix 2 of the UCLA Guidelines For Research Ramp Up that were initially released on May 26<sup>th</sup> (<https://ucla.app.box.com/v/UCLA-Guidelines-Res-Ramp-Up>).

Please note that individual research projects still must follow the procedures and policies described in the UCLA Guidelines For Research Ramp Up to obtain approval to proceed with your research utilizing MRI in the BMC. Per guidance from the DGSOM Vice Dean for Research, Stephen Smale, PIs of individual projects should provide evidence of approval of their projects to the BMC Director, Roger Woods and do not need to include Vice Dean Smale.

### Researchers in the Brain Mapping Center

Any researchers entering the BMC must wear a mask and/or face covering at all times. Hand hygiene should be performed upon entry to the BMC. Any researcher experiencing symptoms of COVID-19 should not come to the BMC. Research staff

should all be enrolled in the UCLA Symptom Monitoring Survey (<https://ucla.app.box.com/s/96on1j6ynhy5c91jdpxxqyi39pl8x796> or, for physicians, the equivalent UCLA Health screening) and provide proof of completion to BMC staff upon entry to the BMC. Research staff will also undergo a fever check by BMC staff upon entry to the BMC.

At this time, we envision BMC staff conducting all MR scanning, with research team members present only remotely (i.e., not physically present in the scanner suite). We recognize that this is a major change and will require extensive advance preparation to assure that BMC staff can properly administer tasks, select the correct imaging protocol, etc. Some studies may simply be too complex for BMC staff to administer and may have to be included in later phases of reopening. During scanning, one member of the research team will be provided with space in Room 131 (the former Data lab, located across the hall from the PET lab) where they can establish a remote connection into the scanner control room and where they will be within earshot of the scanner. Using Zoom and/or other remote connection tools, this research team member will be able to communicate with the subject and potentially to interact with laptops in the scanner suite. This person from the research staff will also serve as the required safety second for the scan (more about this below) from this Room 131 location, so only those who have completed BMC 3T MR safety certification are eligible to serve in this role. Cleaning supplies will be provided in Room 131, and research team staff will be expected to use these on arrival and before leaving; BMC staff will not be responsible for cleaning in Room 131 between scans. Instructions on the cleaning of Room 131 upon arrival and before leaving will be provided to the research staff and posted in the room.

Research groups will not be permitted to scan without BMC tech assistance, and, except in the case of an emergency response, the scanner suite will be strictly off limits to members of the research team. We do not plan to reenable biometric access to the building for research team members at this time; access will be provided by the BMC staff member. BMC staff are already experienced with the disinfecting procedures and other procedure discussed below, and the requirements are sufficiently exacting that we do not currently think that it is feasible to train research team members to follow these procedures independently.

Subject time in the BMC should be minimized, so consent should be obtained and MRI safety screening completed by the research team prior to the subject's arrival at the BMC. Subjects arriving early will be asked to wait outside the building — waiting in the lobby will not be permitted. BMC conference rooms and prep rooms will not be made generally available for research staff to interact with research subjects on site and it is recommended to utilize web-based meeting platforms, such as Zoom, for interactions with subjects prior to the subject's arrival at the BMC. Case-by-case exceptions will be evaluated only for those whose offices are physically located in the BMC.

### Pre-visit and On-Site Screening

All research subjects should be screened for symptoms of COVID-19 infection by your research study staff within 16 hours of their scheduled scan. Screening should use the form provided as Appendix 2A of the most up-to-date version of the UCLA Guidelines For Research Ramp Up, which were initially released on May 26<sup>th</sup> (<https://ucla.app.box.com/v/UCLA-Guidelines-Res-Ramp-Up>).

BMC staff will repeat this screening upon participant arrival, relying both on verbal responses from the subject and on their own observations, including a fever check using a no-contact temperature screener. Fever will be defined as a body temperature of 100.4°F (38° C) or higher. BMC staff will retain documentation of the screening responses, identified only by the date and time of the scheduled MRI study (no subject identifier) so that these can be available for audit if necessary. The BMC scheduling database records the PI, project and consent used for each study, and the research team should keep an identified list of research participants organized by date and time of BMC study in the event that contact tracing were to become necessary. Participants who fail screening will be sent home. To assure that there are no disincentives to cancelling a study due to possible COVID-19 infection, no cancellation fees will be charged for cancellations due to failed COVID-19 infection screenings.

### Disinfection Procedures

As an additional precaution, the disinfection procedures that will be employed by the BMC staff between subjects will be consistent with those procedures recommended for confirmed or presumptive positive COVID-19 patients.

For patients known or presumed to be COVID positive, UCLA Health currently recommends careful cleaning of all surfaces in the scanner suite with an EPA-approved hospital-grade disinfectant, including the interior scanner bore. Linen and equipment must also be carefully managed to avoid exposure. Operationally, this means that scans will need to be separated by gaps of at least 30 minutes and more likely 45 minutes. The changing room where the subject changes into a gown will also be disinfected as a safety precaution. One of the downstairs restrooms will be designated and restricted as a research subject-only restroom and the toilet seat and handle, sink handles, paper towel dispenser handle and interior and exterior door handles will be disinfected by BMC staff before every subject.

### Social Distancing and Safety Seconds

It has been a longstanding Center policy that two MR safety trained people must be present during MRI scanning to assure that an unforeseen subject emergency can be safely managed in the context of the dangers of the strong static magnetic field of the scanner. This policy is in accordance with the American College of Radiology's guidance (<https://www.acr.org/-/media/ACR/Files/Radiology-Safety/MR-Safety/Manual->

[on-MR-Safety.pdf](#)), which indicates that at least two safety trained personnel should be present and within earshot of one another. While it is technically possible for two people present in the scanner control room to remain 6 feet apart from one another, this would result in a personnel density well above one person per 250 square feet, which is a requirement for Phase 2 campus research (see Appendix I of the UCLA Guidelines for Research Ramp Up at <https://ucla.app.box.com/v/UCLA-Guidelines-Res-Ramp-Up>). The BMC policy will therefore be modified to permit the control room hallway door to remain open during scanning with the safety second (from the research team) located within earshot in Room 131 (former Data Lab). Only in the event of an emergency should this second person enter the control room — technical difficulties with computers or other equipment do not constitute such an emergency.

It has been strongly recommended for many years that all subjects change into a BMC supplied hospital gown before MRI scanning to assure that ferromagnetic or other unsafe materials are not introduced to the scanner room's strong magnetic field by the subject. This recommendation will become a requirement to minimize the need for ferromagnetic wanding, which involves close contact with the subject, to detect unsafe items. Subjects will also be provided with disposable foot coverings. Room 120 (old Sonata console room/Trent's office) will be converted into a changing room by removing all items except for an easily cleanable plastic chair. Subjects will be able to lock their belongings in the lockable bin in Room 120 and will proceed directly from Room 120, through the control room and into the scanner room. Upon completion of their scan, subjects will return directly to Room 120 to change back into their street clothes. Disinfection of Room 120 between subjects will include cleaning of the lockable bin and MR safe key in addition to all surfaces, door handles and the chair.

To maximize physical distancing from regular occupants of the Brain Mapping Center, research subjects and research project staff should be instructed to enter and depart the building through the back door, located immediately adjacent to the MR scanner suite. Front door signage will direct research participants to the back door entry.

### Hand Hygiene

Hand sanitizer dispensers are located at both BMC entrances and in the control room at the doorway to the scanner room. A wall mounted dispenser is already located in the changing room (Room 120) and a dispenser bottle will be available in the research staff room (Room 131). Subjects will be asked to clean their hands upon entering the building and upon entering and exiting the scanner room. Soap and water are also available at the sink in the scanner room for subjects who prefer to use soap. BMC staff will likewise apply hand sanitizer or wash their hands before every subject interaction and upon entering and exiting the scanner room. Research staff will also clean their hands upon entering the building and when exiting Room 131.

### Masking and Other PPE

In accordance with current guidelines effective in LA County, all subjects should arrive at the BMC wearing a mask or cloth face covering. Since masks or face coverings that research subjects bring from home might include unsafe ferromagnetic components or be made of material subject to heating in the MR environment, all subjects will be provided an MR safe mask to change into at the same time that they change into a hospital gown. Subjects will be advised to use hand sanitizer before putting on the MR safe mask. This mask should be worn as the subject goes from the control room to scanner room and back again. The subject can be asked to remove their mask and place it on a bedside tray as they are being positioned on the scanner bed and will be asked to replace it as they are getting back up (BMC staff will wear a plastic face shield for added protection while interacting with subjects in the scanner room). Research teams should specify whether it is scientifically permissible for a subject to wear a mask during the scan and whether this is mandatory for consistency across subjects. The research team should discuss masking during the scan with the research subject before the subject's arrival at the BMC. Note that masks may contribute to claustrophobia in some subjects, may muffle clarity of verbal responses, may increase the likelihood of subject motion during scans, and may distract from or interact with performance of functional tasks. We anticipate that most projects will opt against subjects' wearing of masks during scanning for these reasons

BMC staff will wear a mask at all times when interacting with research subjects and will also wear a face shield whenever they are in the scanner room with a subject. Staff will wear clean gloves if it is necessary to touch the subject for positioning purposes. Protective gowns will be available for BMC staff for use at their discretion. BMC staff have been trained on how to safely don and doff PPE following the procedures in the attached documents.

In the event that a research team member has to come to the scanner room in their role as a safety second, an emergency PPE kit will be available in Room 131 that will include MR safe gloves, gown, mask and a face shield. It should be noted that standard surgical masks often have a metallic component that is not MR safe, so the research team member should replace their own mask or cloth face covering with the MR safe one provided when responding to an emergency. The research team member should always remove all non-MR safe items from their person before their research participant enters the scanner room as PPE may distract from removing these items in an emergency setting. Instructions on how to don and doff PPE will be provided in advance and will be posted in Room 131, and are available by links on the BMC website at [http://www.bmap.ucla.edu/services/safety\\_training/mri\\_safety/](http://www.bmap.ucla.edu/services/safety_training/mri_safety/)

### Individuals Accompanying Research Subjects

Having additional people in the BMC space can increase risks and introduce challenges with physical distancing. Research subjects should not be accompanied by a family or household member unless absolutely necessary, and this should be limited to just one

accompanying healthy (adult) person. Like the research participant, the accompanying adult should be screened by the research team for COVID-19 within 16 hours of the scan using the same screening procedure used for the research participant and must not come to campus if they fail screening. The research team should alert the BMC staff to any accompanying individuals prior to the scheduled time of arrival. If the individual is from the same household as the research subject, BMC staff will screen them for COVID-19 as if they were a research subject and they will be permitted to wait in the changing room (Room 120) during the scan. If they are not from the same household, they should wait outside the building. If the research protocol includes permitting a parent or close adult relative to be in the scanner room with the participant during scanning, this person will need to follow all of the COVID-19 related procedures that a research subject would follow, including changing into a hospital gown and wearing a BMC provided MR safe mask.

### Scan Charges

Research projects will not be charged for the gap times between scans. Subjects should arrive long enough before the scheduled scan time to allow sufficient time for the BMC staff to screen them and to use the restroom and change into a gown. Due to the substantial strain placed on the schedule by imposed gaps between studies, it will generally not be possible to allow scans to run beyond their scheduled time, so research teams should schedule sufficient time to complete data acquisition goals.

Per routine, BMC staff members can arrange to work with research groups on protocol development and testing that does not involve running the scanner at no charge during times that the scanner is not booked for research studies. Such protocol testing and development should be done with the research team member offsite by Zoom to the fullest extent possible. For any onsite testing (e.g., of functional tasks), the research team member cannot be in the control room or scanner room and must interact with the BMC staff member from Room 131.

### Subject Restrictions

Subjects who would likely fail to understand or to comply with the physical distancing, masking and other policies above due to age or cognitive issues should not be scanned until the policies above are no longer needed. BMC staff have the discretion to terminate a study at any point for failure to understand or comply with infection control policies. Subjects who would require the assistance of two or more people to safely get on or off the scanner bed cannot currently be scanned. We do not currently foresee the Center imposing any global constraints based on age or health as risk factors for severe illness if a subject were to contract COVID-19—individual research teams are best positioned to help potential research subjects make informed decisions about potential risks and benefits. While it is never feasible to create an environment that is entirely free of risk, the policies and procedures detailed above are intended to reduce the COVID-related risks to low levels comparable to other MR associated risks and comparable to

risks that research subjects will be routinely taking in everyday life. Any infectious disease poses increased risk to certain subjects and while these special precautions have not been implemented in the past for infectious diseases such as seasonal influenza, these precautions are needed to manage the challenges that the current COVID-19 pandemic poses and are based on the evidence for COVID-19 transmission.

### BMC Staff Health Screening and Precautions

BMC staff will participate in the UCLA symptom monitoring survey (<https://ucla.app.box.com/s/96on1j6ynhy5c91jdpxxqyi39pl8x796>) and will screen themselves for fever upon arrival at work. Staff will not report to work if they fail screening and will go home if they have fever or develop concerning symptoms during the day. BMC staff will follow UCLA guidelines requiring them to contact the Infectious Diseases Hotline if they develop fever or other COVID-19 symptoms, or if they are tested positive for COVID-19 at an outside facility. Staff will contact their primary care physician for symptoms that develop after hours. BMC staff will follow the most up-to-date guidelines from the UCLA Guidelines For Research Ramp Up that were initially released on May 26<sup>th</sup> (<https://ucla.app.box.com/v/UCLA-Guidelines-Res-Ramp-Up>) regarding symptoms and exposures for workers participating in research activities (detailed in Attestations section of Appendix 7 – the May 26th version, among other requirements, specifies no COVID-19 symptoms in the past seven days and not contact with positive or suspect-positive COVID-19 individuals in the past 14 days. Since each workday will always start with cleaning procedures, some advance warning will be available if scans must be cancelled due to staff illness. A back-up schedule will be in place, but it may occasionally be necessary to cancel scans at the last minute due to staff illness. Testing of asymptomatic staff for COVID-19, either by PCR for active infection or by antibody testing for prior infection would not currently alter our strategy of treating everyone as if they might have an asymptomatic infection. BMC staff will be following all of the hand hygiene, masking and physical distancing procedures that are recommended by UCLA Health and by the Office of the Vice Chancellor of Research and Creative Activities to prevent spread of an asymptomatic infection. BMC staff will wear masks at all times except when eating or drinking or when in a private room such as an office or single occupant rest room.

### MR Safety Training for New Research Team Staff

MR safety training involves protracted face-to-face contact between BMC staff, the BMC director and the trainees in the scanner room and scanner control room. We are not able to offer training during Phase 2.

### Undergraduate Students and Volunteers

Even if BMC MR safety certified, individuals defined by DGSOM policies to be volunteers (this includes undergraduate students working for credit) cannot serve as a

safety second and therefore cannot serve as the research team member in Room 131. This is consistent with standing BMC policy that BMC staff cannot provide direct supervision for research project volunteers and with the phase 2 requirement to have at least 250 square feet per person.

### Subject to Change

We will continue to monitor new information on an ongoing basis and work towards a return to normal operations as data justifies. The prevalence of community transmission is currently a key variable that sets LA County apart from many other places in the country and is the variable most likely to readily translate into short-term policy changes. Advances in diagnostic testing, in interpretation of diagnostic tests and in understanding of transmissibility are complex to translate into practice, and we will primarily rely on regional and national and local UCLA policies to help integrate appropriate infection control practices into BMC policy while local community transmission remains prevalent. As we see how things work (or don't work), we will make modifications and can start to consider specific expectations to the global policies. Our short term goal is to open a path forward for a substantial fraction of projects; any scanning that we can safely complete in the short term will reduce the future backlog as current restrictions relax.