

Brain Mapping Center COVID-19 Phase 3 Risk Mitigation Plans

It continues to be the case that neither testing nor vaccination status suffice to assure that a research subject, BMC staff member, or research team member cannot transmit COVID-19 to others. Consequently, BMC Phase 3 policies continue to assume that everyone might be infectious.

Research imaging projects in the Brain Mapping Center address major health issues, and the Center remains eager to facilitate research while appropriately managing risks. The definition of appropriate risk management continues to 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 of human subjects 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 3 research in Appendix 2 of the UCLA Guidelines For Research Ramp Up that were initially released on May 26th, 2020 (<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 in that communication.

Policy Changes for BMC Users in Going from Phase 2 to Phase 3

The Phase 3 policies are fully backwards compatible with Phase 2 policies, so research groups wishing to continue existing COVID mitigation practices as before are welcome to do so (note that PI's must obtain approval of a new Phase 3 operational plan covering the research before April 1, 2021). To enhance flexibility and efficiency, the following new BMC COVID mitigation policies are being implemented for Phase 3:

1. An MRI Safety trained member of the research team will be permitted to enter the Prisma scanner room (831 square feet) with justification (e.g., technically challenging set-up of ancillary equipment, scanning of a sensitive subject requiring familiar staff, a need to monitor a subject in person or to administer behavioral tasks in person). This person must pass efficiently and directly through the control room when travelling between scanner room and outer hallway and, when not in the scanner room, should either return to Room 131

(243 square feet) to serve as the safety second or, if someone else is serving as safety second, leave the scanner area (and unless otherwise authorized, the building) entirely. Exceptions to this policy (e.g., having more than one staff member in the scanner room simultaneously), must be approved in advance by the BMC Director (Roger Woods) and must be detailed as part of the research group's approved Phase 3 Operational Plan.

2. The BMC Director (Roger Woods) or the BMC Lead MR Technologist (Trent Thixton) may authorize a member of the research team to substitute for a BMC technologist to run the scanner when a BMC technologist is unavailable on site (e.g., evenings or weekends). Prior BMC-provided training in COVID mitigation and cleaning procedures is a prerequisite for such authorization, and continued authorization is contingent on strictly following all these procedures. Execution of these procedures may **not** be delegated to another member of the research team (even if qualified) nor delayed to perform other activities such as escorting a research subject to another location after the scan. Research team members substituting for BMC staff will be required to complete an on-line form documenting that they have completed post-scan cleaning procedures. This form should be submitted immediately upon completion of cleaning.
3. During Phase 2, the BMC has developed a *provisional* MR safety training program that is administered remotely via pre-recorded video and Zoom. This *provisional* training remains sufficient for those research team members who would only need to enter the scanner room in the case of an emergency when serving as a safety second from Room 131. For members of the research team who would regularly need to enter the scanner suite, the BMC Director or BMC Lead MR Technologist may provide the research team member one-on-one access to the MR scanner room for the purpose of providing *definitive* MR safety training, for providing training regarding COVID clean-up procedures (after remotely watching a BMC-specific COVID-cleaning video) or for providing standard training regarding scanning procedures such as subject positioning or use of ancillary equipment. The BMC staff member providing such training will be responsible for assuring that the room has been cleaned to the normal post-scan standards before the room is released back to operational status.
4. The BMC Director or the BMC Lead MR Technologist may also provide access to the scanner room to allow a member of the research team to train another member of the research team (e.g., on how to connect specialized ancillary equipment, etc). Such training activities must be part of the research team's approved Phase 3 operational plan, which should also provide justification if more than two people need to be in the scanner room simultaneously. A BMC technologist (or research team member authorized to substitute for an MR technologist) must be on site and will be responsible for cleaning the room to the normal post-scan standards before releasing it back to normal operational status.
5. Cleaning after each scan is a critical part of the COVID mitigation plan. When a BMC technologist is performing the scan, the next scan must be scheduled for a time that is at least 45 minutes after the scheduled completion. If a research

team member is substituting for a BMC technologist, the next scan must be scheduled no less than one hour after the prior scan's completion.

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.

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 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 (or *provisional* 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.

Biometric access to the building and scanner suite will only be re-enabled for research team members who are authorized to substitute for BMC technologists to scan on their own, and may only be enabled for evening and weekend hours. Access to any other research team members will be provided either by BMC staff or the authorized research team substitute. The entire MRI suite and back hallway from the MRI scanner to Room 131 are strictly off-limits to anyone not actively involved in an ongoing MRI scan, and the back door of the building should not be used to enter or exit the building's main lobby area.

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, 2020: (<https://ucla.app.box.com/v/UCLA-Guidelines-Res-Ramp-Up>).

BMC staff (or the research team member substituting for a BMC technologist) 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 (or authorized research team substitute) after each subject 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. 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 (or authorized substitute) before and after 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 in the scanner control room to be 6 feet apart from one another, the physical layout of the room would not allow the second person to actively participate in the scanning. Consequently, a modified BMC policy instituted under Phase 2 will remain in effect during Phase 3, permitting 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).

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 is now a requirement. Subjects will also be provided with disposable foot coverings. Room 120 (old Sonata console room/Trent's office) has been 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 after the subject leaves 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 is 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 (staff must 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. In addition, higher carbon dioxide levels from masking can lead to vasodilation, which may be particularly problematic for longitudinal studies of blood flow. We anticipate that most projects will opt against subjects' wearing of masks during scanning for these reasons

Staff must wear a mask at all times when interacting with research subjects and must 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 staff for use at their discretion. BMC staff have been trained on how to safely don and doff.

In the event that a research team member has to unexpectedly 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/

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 needed for cleaning. Subjects should arrive long enough before the scheduled scan time to allow sufficient time for the 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 unless the research team's Phase 3 operational plan provides a procedure for this. 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, 2020 (<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). BMC staff will comply with UCLA requirements for routine COVID surveillance testing. 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.

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.

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 continuing 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.