

Advanced Imaging Research Center *Return-to-Research Plan*
July 22, 2020

Overview of AIRC *Return-to-Research Plan*

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*: Level 0: Normal Operations

This document will be refined as needed to accommodate best practices and as the COVID-19 situation changes at OHSU and in the Community. If any statements within this document conflict with OHSU general guidelines (we have tried hard to be consistent), OHSU guidelines should be followed.

N.B. Version control - The most current version will be available on the OHSU/AIRC wiki.

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1. Modified Operations and Allowable Work

AIRC will be minimally staffed during modified operations Level 1-2 with no more than twelve faculty/staff members in LBRB AIRC space on both levels LBRB Floor 1 and B2 at one time. The maximum for LBRB Floor 1 at one time will be 8 people. The maximum for LBRB Floor B2 will be 4 people. All individuals will maintain physical distancing, wear face masks, and wash hands regularly. Allowable work and modified operations at Levels 0-3 are detailed in Table 1.

AIRC will follow OHSU Infection Prevention Policies and Occupational Health Policies to minimize infection risks to human subjects and research staff. The investigators should consider MRI study-related questions in Appendix A, B, and C in preparing PI plans to restart human, animal, and inanimate (phantom, fixed tissue, QA/QC, etc.) MRI studies, respectively.

Table 1. AIRC Normal-Modified operations and allowable work

	Level 0 Normal	Level 1 Modified	Level 2 Modified	Level 3 Modified
Data Analysis, Consultation ^A	OK	OK	OK	OK
Data Acquisition Inanimate ^B	OK	OK	OK	No
Data Acquisition Small animal ^C	OK	OK	OK	Exception needed
Data Acquisition Human Subject Typical Community Risk ^D	OK	OK ^F	OK ^{F,G,H}	No
Data Acquisition Human Subject High Risk ^E	OK	OK ^F	OK ^{F,G,H,I}	No

A – At levels 1-3 all work done remotely.

B - This work is largely developmental in nature, programming MRI instruments for specific acquisitions and validating using inanimate (phantom or fixed tissue specimen) samples. Minimal interaction among staffs and physical distancing guidelines as per OHSU Infection Prevention Policies and Occupational Health Policies will be followed.

C - This work would be done primarily in the 12T MRI area on LBRB B2. At most two researchers would be present in a large room (375 sq ft; see Appendix D) and physical distancing guidelines and PPE (including face masks) would be followed. Sufficient time gap will be implemented between operational personnel change/rotation to allow disinfection and cleaning. No new experiments, but ongoing studies are allowed at Levels 2 and 1.

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D – This work would be done primarily in the AIRC 3T (LBRB Floor 1) or AIRC 7T (LBRB B2) laboratories (see Appendix D). Human Subject “Typical Community” Risk is defined as ambulatory, not elderly (< 65 y), has no known medical conditions that increase infection risk beyond that experienced in the typical community (i.e., “Typical Community Risk” subjects in parlance of Research Levels 1 to 3 Modified Operations: Human Subjects Research Draft dated May 1, 2020). It is the PI’s responsibility to determine the risk category for their study participants.

E – Human Subject “High Risk” is defined as vulnerable to severe disease from COVID, including the elderly (65 y or older), subjects with underlying medical condition consistent with CDC definition of “high risk” subjects (<https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/people-at-higher-risk.html>), non-ambulatory, etc.). It is the PI’s responsibility to determine the risk category for their study participants.

F - Physical distancing guidelines and OHSU policies would be followed for any human subject visits. It is expected that human subjects and accompanying visitors would arrive in personal vehicle. The subjects would enter the LBRB through the main door on Floor 1 (Appendix D). Access to 7T requires transit using an elevator; maximum occupancy limits would be adhered to and face mask or covering would be used. It is expected that the AIRC study visit risk is not greater than visiting a grocery store. A 30-min time gap in scanner scheduling is required between different subjects to allow thorough disinfection/cleaning and magnet bore air to turn over.

G – If more than one research staff member needs to have in-person interaction with the human subject and/or family members from the same household, the interaction should be sequential.

H – Group research activity may not occur at Level 2, unless an exemption is approved by the COVID Clinical Research Task Force. Group refers to in-person activity among more than one human subject household and one or more research staff members.

I – At level 2, the consideration of the risk to the individual subject is a decision between the study team and the research subject, rather than requiring an exception approved by the Clinical Research Task Force.

2. General New Staff Requirements (all Levels 1-3)

A. Designation of AIRC Critical Staff

AIRC will ask staff who can work from home to continue working from home during the transition. Critical staff will work on campus for only the hours they need to be there to complete work that must be done on site. Individuals needed to start operations are delegated below:

12T Operations: Tom Barbara, Martin Pike

3T Operations: Eric Baetscher, Josh Emmons, William Woodward

7T Operations: Eric Baetscher, Josh Emmons, Daniel Schwartz, Manoj Sammi, William Woodward

Computing: Brendan Moloney, Eric Baker

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Management & Administration All Operations: Bill Rooney, Laura McMahon

Cryogenics and System Maintenance: Tom Barbara, Bill Rooney, Eric Baetscher, Xin Li, Siemens Service, Jingang Xu

B. Health Monitoring of AIRC Critical Staff

AIRC staff will follow OHSU guidelines for returning to work (<https://o2.ohsu.edu/covid-19/employee/upload/Guideline-for-Non-Healthcare-Employees-Returning-to-Work.pdf>). If an individual has been tested positive or developed symptoms consistent with COVID-19 (including cough, fever, shortness of breath, chills, repeated shaking with chills, headache, sore throat, muscle pain, and new loss of taste or smell), this individual must not come to work or leave work immediately, and inform the AIRC administration. Another staff member will rotate in. Anyone who is exposed to an individual with positive coronavirus test will also rotate out. Staff will stagger shifts as to minimize possibility of multiple staff being exposed, with the only exceptions being for operational safety concerns.

C. Staff Time on Campus Log

Each staff member will log his/her times of arrival and departure from AIRC in an electronic log book (a formatted Excel Sheet on Box), which will be monitored by Laura McMahon daily and apparent deficiencies communicated to associated staff and AIRC Director. Staff time on campus should be minimized to accomplish tasks that cannot be performed remotely. This information is important to track the number of individuals at the AIRC during any given period, and to facilitate contact tracing if needed.

D. Personal Protective Equipment (PPE)

All individuals (OHSU personnel, human subjects, visitors, service engineers) must wear a mask covering the nose and mouth while in the AIRC. The mask or face covering worn in the magnet room (Safety Zone 4) must be MR-compatible. Masks will be provided by the AIRC for staff and visitors. For personnel within single occupancy offices within the AIRC, masks may be removed when the door is closed. Gloves should be worn by staff when dealing with human or animal subjects. Hand sanitizers will be available for use throughout AIRC spaces. All staff should use hand sanitizer and wash hands frequently.

E. Physical Distancing and use of common areas

AIRC staff will practice physical distancing (>6 ft apart) from OHSU personnel and visitors at essentially all times. Procedures requiring close physical distances, such as subject positioning in the MRI instrument, represents an exception and is expected to be performed efficiently (minimizing contact time and planning procedure ahead of time) and with approved PPE (masks, gloves, lab coats, and eye protection). Gloves are to be properly removed and discarded immediately after such procedures. It is typical for studies to require two people be present in the MRI control room during data collection, and during this time personnel will maintain physical distancing of at least 6 feet. Acceptable seating locations in the MRI control rooms will be demarcated by tape.

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Hallways, bathrooms, and common building areas. Approved face masks covering the nose and mouth will be used in all OHSU building hallways and common areas in accordance with OHSU policies. Physical distancing of 6 feet or more should be observed in public bathrooms whenever possible (unless within adjacent singly-occupied stalls), and hands should be washed just before leaving the bathroom.

Meals and snacks. AIRC personnel will take their meals/snacks at their office desk, or weather permitting, on the LBRB patio. Research subjects will take their meals/snack in the AIRC conference room (LBRB107; Appendix D). The Interaction Room (LBRB125; Appendix D), typically used for meals/snack, now will be reserved as a hand-washing area; staff should not spend prolonged time in this room and the Interaction Room should not be used for meals.

Non-AIRC personnel and visitors. It is expected that non-AIRC personnel and visitors will be present within the AIRC for the minimum amount of time needed to complete the MRI study. Research volunteers will be encouraged to have a minimum number of family/friends accompany them during an MRI study visit.

F. AIRC Infection Control/Sanitization Methods

See Appendix E.

G. Transportation

Except when OHSU is at Level 3, parking may not be free and open to critical staff. Therefore, AIRC staff will rotate the use of the AIRC parking spot. Any individual who has a designated parking space will need to use that parking spot. Whenever possible, AIRC staff and faculty should avoid the use of public transportation during this transition time. Biking, walking, ride shares are encouraged.

3. Prioritization of Restarting Research

With implementation of 30-min gap between human MRI studies, MRI instrument availability may not meet community demand. AIRC will increase operation hours as needed to better accommodate demand, but as courtesy to our operators we request that schedulers keep MRI sessions as clustered as possible. If instrument access is insufficient to meet community demand, AIRC will implement prioritization policies for restarting research that follow the OHSU guidance, as well as meet the center's current operation practice and users' specific needs. These priorities will be developed in consensus with the MRI research community, but may include the following:

- *During transition from Level 3 to Level 2:*

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- Continue to prioritize pilot data acquisition for COVID-19 research.
- Active grant-supported work and deadline-driven work for grant submissions and manuscript submissions.
- Data collection needs for writing manuscripts/dissertations.
- Priority given to funded studies over unfunded studies such as development –time studies.
- Priority will be given to OHSU investigators over external users during transitional period.
- *During transition from Level 2 to Levels 1 and normal operation (level 0):*
 - With input from the user community, continue to create priority structure to restart MRI studies in a staggered manner to prevent overwhelming AIRC services.

Information gathered from PIs' plans to restart research, taking into consideration responses to questions posted in Appendix A – C, will be used by AIRC to evaluate study priority. Some studies with vulnerable human populations or animal surgical procedures requiring significant DCM and multi-person involvement may need to be evaluated and approved through an exception process and include a plan to address potentially significant safety and staffing issues.

4. Communications with AIRC User Community

AIRC will hold virtual PI meetings to discuss guidelines for restarting research and to obtain feedback from the user community. A final version of the policy will be posted on AIRC's website and distributed to the user community so that users are aware of the restart procedures. This AIRC policy will be updated as needed to be in compliance with up-to-date University guidelines on research during COVID pandemic.

As modified operations levels shift and OHSU begins to open up research, AIRC will do its best to reach out to users whose protocols may align with the conditions of the announced research operation level. However, it is the users' responsibilities to monitor OHSU leadership's announcements and contact AIRC when they believe that they are now able to restart their MRI studies. This is especially important as the PIs and study staff best know their subjects' demographics and health conditions, study protocols, and safety issues that are relevant to the current modified operation level.

Scheduling in iLab may be restricted to prevent users from scheduling MRI studies before the request of study restart is evaluated. Normal scanning hours may also need to be restricted to fulfill social distancing and infection mitigation requirements.

Reservation fees for canceled scans will continue to be waived for any COVID19 related cancellations. This is to promote emphasis on safety of all research staff and subjects.

5. Process for User Request to Restart MRI Studies

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Users whose protocols are allowable under OHSU modified operations levels will work with AIRC staff to develop plans specific to their needs while maintaining safety. Initial study scheduling will require more discussions than was previously done (i.e. just scheduling in iLab and AIRC Operators Outlook calendar) and will be evaluated on a case by case basis.

To initiate the restart of study/studies, investigators should email the PI Plan for Restarting Research and its departmental approval to the following AIRC members. To facilitate AIRC evaluation of the request, the questions in Appendix A, B, and C for different types of studies should be addressed in the PI Plan.

- **For human MRI studies:** Email Laura McMahon, Bill Rooney, and Wei Huang
- **For animal MRI studies:** Email Marty Pike, Bill Rooney, and Laura McMahon
- **For fixed tissue, phantom, QA/QC, and development studies:** Email Bill Rooney, Wei Huang, and Laura McMahon

6. Additional Human Subject Study Guidelines

In addition to normal MRI safety screening and research subject preparation procedures, it is the PIs' responsibilities to follow university policies and CDC guidelines in screening human subjects, as well as their staff members who accompany the human subjects to AIRC, for COVID-19 symptoms and/or COVID-19 test results to minimize risks for virus transmission during MRI study procedures in AIRC. Each research group has individual responsibilities for their human research subject interactions and preparations such as:

- Screening potential human subjects before coming to campus via current OHSU policies, e.g., phone screening for COVID19 symptoms as per CDC guidelines (such as fever, cough, shortness of breath, etc.), exposure to individuals with confirmed COVID-19 diagnosis, and COVID-19 test results if available. Subjects should also be screened for asthma, heart conditions, immunodeficiency, and other known pre-existing conditions that make human subjects more vulnerable to COVID19.
- Limiting visitors in AIRC (i.e. only research subject or research subject and parent or guardian, or partner living in the same household)
- Limiting study staff in AIRC (i.e. only one study coordinator if possible)
- Study staff, human subject, and visitor should wear PPE (i.e., mask or face covering) at all times while they are inside AIRC. Research groups will be responsible for providing PPE to their study staff, human subjects, and visitors before arriving at AIRC and for ensuring they wear PPE inside AIRC. AIRC will provide PPE if there is a need.
- Bringing subjects to the AIRC. This should be done with minimal exposure to clinical areas (i.e., using outdoor access to LBRB through Floor 1 doors vs. walking through hospital areas and indoor corridors)
- It is encouraged to have clear communications with human subjects to ensure they notify study staff if they test positive for COVID19 and/or develop typical COVID19 symptoms within 14 days of their AIRC visit. If anyone tests positive and/or develops symptoms, the human subject and/or study staff, the study staff is required to inform AIRC staff so that they can take precautions and quarantine.

Appendix A

Questions Relevant to Restarting Human MRI Research

1. Review the medical/health conditions of your human subjects.
2. How do you plan to screen for pre-existing conditions and COVID19 symptoms?
3. How many of your staff are needed minimally at AIRC to proceed with your study?
4. Does your study require an AIRC operator or faculty/staff member? Does your study need an intravenous injection of contrast agent or other substance? Does your study need a rapid test of kidney function?
5. Do you have a special exemption approved by the OHSU COVID Clinical Research Task Force to conduct research that is not allowed at the current Modified Operations Level?
6. Can the additional human subject study guidelines outlined in this document be followed in full? Please describe any issues to adhere to these guidelines.
7. Any other specific details of your human MRI study that may increase the risk of COVID-19 infection in AIRC?

Note: All staff must follow OHSU return-to-work safety guidelines.

Appendix B

Questions Relevant to Restarting Animal MRI Research

1. Do you require DCM assistance for surgical procedures (pre- or post-scan included)?
2. Which MR instrument will you use?
3. How many of your staff are needed minimally at AIRC to proceed with your study?
4. Does your study require an AIRC operator or faculty/staff member?
5. Do you have a special exemption approved by the OHSU COVID Research Task Force to conduct research that is not allowed at the current Modified Operations Level?

Note: All staff must follow OHSU guidelines, as well as DCM specific policies, for return-to-work safety.

Appendix C

Questions Relevant to Restarting Inanimate MRI Research (fixed tissue samples, phantoms, development, QA/QC, etc.)

1. Which MR instrument will you use?
2. How many of your staff are needed minimally at AIRC to proceed with your study?
3. Does your study require an AIRC operator or faculty/staff member?

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Note: All staff must follow OHSU return-to-work safety guidelines.

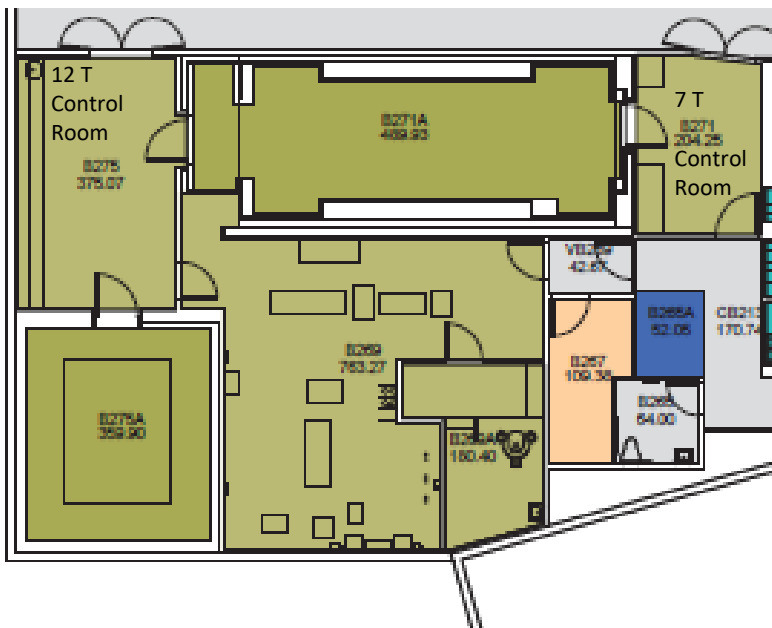
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Appendix D: AIRC Floor Plans

LBRB B2 Level



AIRC Space on LBRB B2



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LBRB First Floor



AIRC Space on LBRB First Floor (semi-transparent areas at image left not part of AIRC)



Appendix E: AIRC Infection Control/Sanitization Methods

An MR-compatible mask or face covering will remain in place on operators and study staff during the MRI study. The research human subject will be required to wear a mask or face covering through Safety Zone 3. AIRC will provide the subject with an MR-compatible mask to wear in the magnet room (Safety Zone 4) if requested. A separate writing utensil will be reserved for research subjects and disinfected after use. In addition, AIRC will increase disinfection/sanitization of AIRC spaces to include:

1. Subject Waiting Areas, Floor 1 LBRB, Floor B2 LBRB: all doorknobs, light switches, couches, tables wiped down with sanitizing wipes between research subjects and/or after all the day's procedures are complete. Garbage taken out nightly.
2. Subject Prep Rooms, Floor 1 LBRB, Floor B2 LBRB: all doorknobs, light switches, writing utensils, surfaces, phone, refrigerator, IV chair, drawer and cabinet handles, scale, bathroom sink, toilet cleaned in between subjects and nightly.
3. 3T, 7T Control Rooms: all doorknobs, light switches, keypads, computer and accessories, intercom, writing utensils, telephone, and surfaces sanitized between subjects and at end of day.
4. 3T, 7T Magnet Rooms: all doorknobs, RF coils, pads, MRI table, magnet bore, buttons, any applicable peripheral devices, emergency squeeze ball, headphones and surfaces sanitized between subjects and at end of day.
5. 12T Suite: all doorknobs, light switches, keypads, computer and accessories, telephones, animal preparation accessories and equipment, coils, pads, MRI table, buttons, and surfaces sanitized between subjects and at end of day.
6. Mock Scanner room: all doorknobs, light switches, surfaces, MRI table, accessories, phone sanitized between subjects and nightly.
7. AIRC Interactive Room: kitchen sink, handles, microwave buttons, fridge handle, water cooler, light switches, surfaces sanitized daily.
8. Personal desk space: critical staff will also sanitize their personal desk space (keyboard, mouse, phone, surfaces, doorknobs) daily after shifts.
9. AIRC conference room: computer and accessories, chairs, presentation controls, telephone, and surfaces sanitized after each use.
10. Other AIRC spaces (i.e. Chemistry Lab, Electronic Lab, Small Animal Prep, and Machine Shop). all doorknobs, light switches, keypads, computer and accessories, animal preparation accessories and equipment, instrument control interfaces, refrigerator handles, and benchtop surfaces sanitized between use and at end of day

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Infection Control/Sanitization Log

Subject Waiting Area/Subject Prep Room Floor 1 LBRB

[illegible]

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Infection Control/Sanitization Log

Subject Waiting Area/Subject Prep Room Floor B2 LBRB

[illegible]

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Infection Control/Sanitization Log

3T Control Room/3T Magnet Room Floor 1 LBRB

[illegible]

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Infection Control/Sanitization Log

7T Control Room/7T Magnet Room Floor B2 LBRB

[illegible]

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Infection Control/Sanitization Log

12T Control Room/Suite Floor B2 LBRB

[illegible]

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Infection Control/Sanitization Log

Mock Scanner Room Floor 1 LBRB

[illegible]

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Infection Control/Sanitization Log

AIRC Conference Room Floor 1 LBRB

[illegible]

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Infection Control/Sanitization Log

AIRC Interactive Room Floor 1 LBRB

[illegible]