Marquette University Ramping Research Plan

Marquette University Ramping Research (MU-RR) Plan is designed to enable transitions in the level of in-person research activities based on guidelines designed to be responsive to changing public health recommendations (federal, state, and local guidance and requirements) and the University’s COVID-19 Response and Recovery Teams planning. The draft plan has been developed by a team assembled by the vice president for research and innovation (VPRI) and includes subgroup of associate deans for research, select faculty, and university staff from areas included research compliance, risk management, and environmental health and safety. Additional key stakeholders included academic leadership, facilities planning and management (FPM), the dean of the libraries, and other operational areas are also being consulted during the planning process. Note that planning for the libraries is not included in this document; Dean Janice Welburn is working with her leadership team to plan for increasing access to library resources.

This plan provides guidance for on-campus laboratory-based activities, work with human research participants (on and off campus), other field work, and use of the Animal Resource Center.

Guiding Principles for the MU-RR Plan

Principle #1: Recommendations and guidelines must adhere to local government and public health directives.

- Physical distancing means at least 6 feet of distance between individuals within research space and office areas.
- Physical distancing may require work schedules that are staggered in time and space.
- Plans for physical distancing in shared research space will require coordination with all participating laboratory groups.
- Face masks will be worn in all public areas such as hallways and restrooms and may also be required in research spaces. General mask usage will follow University Recovery guidelines as well as Milwaukee or Wisconsin requirements. More specific recommendations for personal protective equipment (PPE) for work involving human research participants will be provided and resumption of existing protocols or starting new protocols will require review of PPE plans.
- Consistent and regular handwashing is expected throughout all phases of the plan.

Principle #2: The research community includes faculty, staff, students, and human research participants who must all do their part to help mitigate the spread of COVID-19. University COVID-19 Recovery Plan policies and procedures will be followed.

- Remote work will continue to the maximum extent possible until research activities return to full operations.
- Daily screening of all researchers and research participants returning to campus will follow the University’s Recovery Plan.
• Since some individuals may not be comfortable with on-site work, particularly during Safe-at-Home orders, participation in laboratory activities is voluntary during initial phases of research ramp-up. Graduate students and other trainees are particularly vulnerable and must not be made to feel that participation is required.
• Shared laboratory workspace, keyboards, etc. must be wiped down by the worker with 70% ethanol or similar antimicrobial solution prior to commencing work, and after finishing work. FPM will provide cleaning materials and guidance for proper usage in laboratory and other non-public spaces not maintained by FPM personnel.
• Faculty/Principal Investigators (PIs) are responsible for educating and training research personnel and monitoring compliance. Faculty will provide a list of laboratory personnel, paths taken by personnel to reach research spaces, laboratory facilities, and bathrooms used by research personnel to their Department Chair to identify high-traffic areas in need of more intensive cleaning and to coordinate use of space. All research personnel must complete Marquette’s Faculty/Staff/Student training and to confirm that they understand these requirements by completing the verification form.
• Faculty/PIs must be prepared with contingency plans in the event of a COVID-19 resurgence and/or need to ramp-down research activities. In addition, the research community is expected to be responsive to modification of this plan due to changing COVID-19 guidance/requirements.

Principal #3 This plan is designed to be a phased ramp up of research activities and not all researchers will be able to be on campus simultaneously until we reach Stage 4 Steady State status. In cases where space limitations, use of shared facilities, or department or building level density concerns require prioritizing on-campus access, the following considerations will be considered when determining access priority.
• Research groups with current external funding.
• Assistant professors.
• Graduate students nearing completion of their degree programs.
• Upcoming deadlines for new or renewal grant applications.

Principal #4 Researchers must plan for ramping up AND ramping down activities. Given the fluidity of the COVID-19 situation, researchers must carefully develop on-going planning that allows for moving back into remote activities or other limitations that may arise.

Overview of Ramping Research Plan

MU-RR consists of a series of stages and allows for ramping-up as well as ramping-down transitions as the COVID-19 public health indicators require. The plan provides guidance for general campus laboratory research activities, work with human research participants, and use of the animal care facility. Details are subject to change at any time if public health guidance changes or University policies are updated. The MU-RR plan will be monitored and updated as appropriate due to the continuing evolution of best practices under COVID-19. The proposed stages for the Ramping Research Plan are shown in Figure 1.
MU-RR Stage Details

MU-RR Stage 0: Critical Maintenance-Only Restriction

Restriction to only critical maintenance of equipment and irreplaceable cell and animal lines, with no additional research activities permitted, constitutes MU-RR Stage 0. This stage would be necessary if more restrictive orders were mandated and has not been implemented to date.

MU-RR Stage 1: Limited Essential Research and Maintenance

MU-RR Stage 1 was announced March 24, 2020 as the “Research Ramp Down.” Guidance provided at that time is included as Appendix A. Stage 1 as articulated in this document also now includes planning for the transition to additional in-person activities enabled by later stages and an opportunity to update essential activity lists. Faculty/PIs will be required to request approval for increased activities in Stages 1-3. Stage 1 planning and updates to the essential activity lists should use the master spreadsheet already in place; Stage 3 requests will utilize Appendix B and can be submitted as a modification of previously approved Stage 2 requests.

In Stage 1, All Marquette University research facilities are restricted to essential activities only. Stage 1 strongly emphasizes remote research activity. Researchers engaged in essential projects must be approved by department/college leadership and logged into the Office of Research and Innovation master spreadsheet. The following principles will be followed:

- Research that can be done remotely, outside the research facilities, will be conducted remotely.
- Participation in approved essential laboratory activities is considered voluntary at this stage. Faculty are strongly encouraged to build plans for graduate students that enable them to continue their research activities remotely. Safety concerns raised by students, faculty, or staff should be forwarded to department chairs or associate deans for research so that they can be addressed.
• University screening will be required as soon as University policies and procedures are set.
• The maintenance of research resources that cannot be shut down without severe impact is considered essential and can continue. Examples include:
  o Equipment that requires on-going maintenance.
  o Cell and animal lines that cannot be replaced.
  o In-progress long term data collection where shut-down would risk losing data.
  o Research activities involving human subjects that can continue in Stage 1 include records review, assessment, testing, or surveys conducted without physical proximity to human participants (i.e., online, telephone, or videoconferencing). Remember that changes to an approved protocol must be approved in advance by the IRB as an amendment to the study, unless they are necessary to eliminate immediate apparent hazards to participants. Should you determine that changes in your procedures are required to reduce the risk of human subject exposure to COVID-19, you can implement them immediately, without prior notice to or approval from the IRB. You will need to ensure that you are not introducing other risks, and you may need to ask participants to sign revised informed consent forms. The changes should be reported to the IRB as soon as possible and the IRB may request a formal amendment. If you have any questions about whether a remote option is possible or approvable (especially for consent), contact the IRB.

Once a date has been determined for Stage 2 ramp up, additional essential activities may arise. Any additional essential research projects must be approved by department/college leadership, reviewed by the VPRI, and after VPRI approval, logged into the spreadsheet maintained by the Office of Research and Innovation. Note that access to research facilities is still severely restricted at this time. The following will be considered as possible essential research activities.

• Additional time sensitive research activities reviewed and approved at the college-level and by the VPRI.
• Modification of maintenance of research resources required for critical research that will begin at Stage 2. Examples include:
  o Changes to equipment maintenance procedures.
  o Alterations in breeding or culture schedules.
• Orders of personal protective equipment or other equipment required to conduct research safely.
  o Arrangements must be made for shipping and receiving orders in a safe manner.
• PIs should build in time for safety SOP training – this will require those returning to campus to review existing safety policies and procedures as well as new requirements for working on campus during COVID-19 restrictions.

Animal Resource Center considerations for Stage 1 planning in anticipation of Stage 2 transition:
  a. Animal Resource Center will create a “Safety Guidelines – working in the ARC during COVID-19” document that will need to be reviewed and signed by all research faculty, staff, and students that wish to continue work in any of the ARC facilities.
  b. Animal breeding may not commence without coordination with the ARC Director and will be contingent on the ARC having sufficient staffing and supplies to support the scaling up of
breeding colonies. Animal ordering will only be permitted with direct coordination of the ARC Director and department Chair to determine necessity.

c. Time-sensitive animal research experiments and/or procedures may begin during Phase 1 and must follow all physical distance guidelines as noted above. Animal research activities (i.e., experiments or surgeries) will need to be reviewed by the Department Chair and coordinated with ARC Management to ensure compliance with all safety and social distancing guidelines and PPE requirements. Plans for this essential work must be reviewed and approved by college leadership and forwarded to the Vice President of Research and Innovation for final approval.

Full details of the Animal Resource Center plan are found in Appendix C.

**MU-RR Stage 2: First stage of increased in-person activities – expanding allowed essential activities**

MU-RR Stage 2 represents the first step in controlled increase of in-person research activities by providing increased essential research work involving time-sensitive activities. Stage 2 is anticipated to begin June 1, 2020, pending campus COVID-19 leadership approval and assuming no significant negative changes in public health indicators.

Requirements for Stage 2 are outlined below. Note that in cases where access needs to be limited due to building density, facility layout, or other concerns, the priorities of guiding principle 3 in the introductory material above will be applied when determining scheduling. Each faculty member (PI) participating in Stage 2 activities will be required to submit a proposed plan for her or his group (see Appendix B). Plans will be reviewed by college leadership (department chairs, associate deans for research, deans as appropriate for each unit) and the VPRI prior to final approval. For the purposes of MU-RR Stage 2 and beyond, undergraduate students may be identified as research personnel and are expected to follow all guidelines and requirements as any other research personnel. Due to the University restrictions on in-person academic program delivery and the potential for needing to ramp down if COVID-19 circumstances warrant, it is recommended that undergraduates not enroll in independent study or other credit-bearing offerings during the summer unless the learning outcomes are based on remote work.

**General laboratory guidance**

- All research that can be done remotely (i.e. not requiring in-person activities), outside of Marquette facilities or any off-campus field sites, will continue to be conducted remotely.
- Research meetings, including laboratory meetings, will continue to be conducted online from remote locations.
- Since some individuals may not be comfortable with on-site work, participation in laboratory activities continues to be voluntary during this phase. Graduate students and other trainees are particularly vulnerable and must not be made to feel that participation is required. Concerns should be forwarded to department chairs and/or associate deans for research.
- Anyone entering the facility must complete the University’s screening process prior to starting work each day. PIs are responsible for developing and overseeing a plan to implement this screening for their research team.
- Individuals developing COVID-19 symptoms while at work must leave the facility immediately and follow Marquette’s guidance.
• Physical distancing measures, wearing face masks, and frequent handwashing must be strictly maintained (see Guiding Principle 1 in introductory material above).
• No more than two researchers are allowed in a laboratory (single room) at the same time. This is contingent on sufficient space in the room to accommodate physical distancing requirements. Shared (core) facilities will require a plan for determining access schedules and expectations for cleaning.
  o It is expected that faculty will be on campus regularly to ensure compliance with ramping plans if the faculty member is not one of the individuals in the laboratory itself. Faculty should discuss in advance with their chair or associate dean for research if this is not feasible.
  o Personnel in the laboratory must wear a face mask while in the laboratory with others (unless this is deemed unsafe by the faculty).
  o A safety plan, including check-in process (buddy-system) must be reviewed by department chair or associate dean for research and followed in any case where only one person is present at a time in a laboratory room. This is normally expected as part of laboratory safety protocols.
• Laboratory workspace sanitization protocols must be strictly followed (see Guiding Principle 2 in the introductory materials above).
• Faculty are responsible for educating and training personnel in their lab to ensure compliance (see Guiding Principle 2 in the introductory materials above).
• Faculty will provide a list of laboratory personnel, paths taken by personnel to reach laboratory facilities, and restrooms and other common areas used by laboratory personnel to their department chair or associate dean for research as part to their request for on-campus research access.
• Each department must have a purchasing/receiving plan that is reviewed by college and FPM in order to ensure safe practices for obtaining research equipment and supplies.

Work with Human Research Participants
• Appendix B includes a section for requests for re-activation of protocols involving human research participants. Limited IRB-approved face-to-face research activities for research involving human participants, in terms of participant recruitment and data collection, may be granted after review by college leadership and the VPRI for ongoing time-sensitive projects if either of the following conditions are met:
  o One-to-one meeting between researcher and participant in which strict social distancing measures are met, including maintaining 6 feet distance and the use of face masks, OR
  o Studies that do not allow for social distancing must have an approved PPE plan. Additional Guidance for PPE planning is shown in Appendix D.
  o In cases where safety of research participants requires two researchers present in the same room, college leadership and the VPRI will review and may approve an exemption to allow three people to be in the same room.
• Screening procedures must be strictly adhered to when engaging in face-to-face meetings. Participants considered at high-risk may not be allowed to participate in research activities. An example screening guide is found in Appendix E.
• Research that is conducted at non-Marquette clinical sites should follow the guidance and requirements of those sites.

Field Work and Community-Based Research (off-campus research activities)
• Field work that does not involve human research participants should adhere to general laboratory limitations (up to 2 researchers in one location, use of face masks and other appropriate
PPE, screening prior to in-person activities) and adhere to any local regulations that may provide additional limitations. Plans for field work should be reviewed by college leadership and the VPRI in advance. Community-based research activities involving human research participants should follow the human research participants guidance above.

Work in the Animal Care Facility (See Appendix C for additional details)

- Animal breeding may not commence without coordination with the ARC Director and will be contingent on the ARC having sufficient staffing and supplies to support the scaling up of breeding colonies. Animal ordering will only be permitted with direct coordination of the ARC Director and department Chair to determine necessity.
- Time-sensitive animal research experiments and/or procedures may continue during Phase 2 and must follow all physical distance guidelines as noted above. Animal research activities (i.e., experiments or surgeries) will continue to be reviewed by the Department Chair and coordinated with ARC Management to ensure compliance with all safety and social distancing guidelines and PPE requirements. All work will continue to need Vice President of Research and Innovation approval.

A review by-building of consolidated department or college requests will take place prior to approving the start of Stage 2 activities. See Appendix F for details.

MU-RR Stage 3: Phased increase in essential research activities

Stage 3 represents an additional controlled increase of the number of research personnel allowed to work in-person. The VPRI will, in consultation with the University’s COVID-19 Recovery Team, determine the timeframe for transition to Stage 3. This timeline will be determined following an evaluation of the level of strict adherence to Stage 2 requirements, current public health status, and the University’s capacity to support the increased level of activity.

All of the COVID-19 protections outlined in the introductory material and description of Stage 2 general laboratory guidance will remain in force. Daily screening of researchers and research participants, physical distancing, sanitization protocols, and wearing of masks in shared areas remain in force. Stage 3 allows for an additional person in each laboratory at the same time, assuming that the room configuration allows for safe work. The request form in Appendix B will be utilized to evaluate and approve new Stage 3 activities; review by department chairs, associate deans for research, and the VPRI will continue to be required prior to initiation of additional Stage 3 activities.

General Laboratory Guidance
This guidance may be adapted prior to, or during, implementation based upon best public health practices and University policy.

- All research that can be done remotely (i.e. not requiring in-person activities), outside of Marquette facilities or any off-campus field sites, will continue to be conducted remotely.
- Research meetings, including laboratory meetings, will continue to be conducted online from remote locations.
- Since some individuals may not be comfortable with on-site work, participation in laboratory activities continues to be voluntary during this phase. Graduate students and other
trainees are particularly vulnerable and must not be made to feel that participation is required. Concerns should be forwarded to department chairs and/or associate deans for research.

- Anyone entering the facility must complete the University’s screening process prior to starting work each day. PIs are responsible for developing and overseeing a plan to implement this screening for their research team.
- Individuals developing COVID-19 symptoms while at work must leave the facility immediately and follow Marquette’s guidance.
- Physical distancing measures, wearing face masks, and frequent handwashing must be strictly maintained (see Guiding Principle 1 in introductory material above).

- Up to three people are allowed in a laboratory at the same time, contingent upon ability to appropriately physical distance.
  - It is expected that faculty will be on campus regularly to ensure compliance with ramping plans if the faculty member is not one of the individuals in the laboratory itself. Faculty should discuss in advance with their chair or associate dean for research if this is not feasible.
  - Personnel in the laboratory must wear a face mask while in the laboratory with others (unless this is deemed unsafe by the faculty).
  - A safety plan, including check-in process (buddy-system) must be reviewed by department chair or associate dean for research and followed in any case where only one person is present at a time in a laboratory room. This is normally expected as part of laboratory safety protocols.
- Laboratory workspace sanitization protocols must be strictly followed (see Guiding Principle 2 in the introductory materials above).
- Faculty are responsible for educating and training personnel in their lab to ensure compliance (see Guiding Principle 2 in the introductory materials above).
- Faculty will provide a list of laboratory personnel, paths taken by personnel to reach laboratory facilities, and restrooms and other common areas used by laboratory personnel to their department chair or associate dean for research as part to their request for on-campus research access.
- If not previously done in Stage 2 approvals, each department must have a purchasing/receiving plan that is reviewed by college and FPM in order to ensure safe practices for obtaining research equipment and supplies.

Work with Human Research Participants

- Field, clinical, and community-based research with human participants can begin in which social distancing can be maintained (6 feet distance between researcher and participant) and/or risk mitigated to a minimal level, as well as in adherence with local and setting guidelines.
  - Screening procedures remain in place as in Stage 2.
  - Research activities when social distancing not possible require approved PPE plan.
- New research projects (as well as existing projects that have been paused) that require face-to-face contact can be initiated so long as they adhere to the previously established guidelines and review and approval processes.
- The number of researchers and participants occupying the same room at the same time should follow the general laboratory limits above. Requests for studies that require more people together at the same time will be reviewed by college leadership and the VPRI.
• A detailed SOP for working with human research participants (Appendix G) and a COVID-19 risk information sheet for research participants (Appendix H) have been created and reviewed by the Marquette COVID-19 medical team.

Field Work and Community-Based Research
• Field work that does not involve human research participants should adhere to general laboratory limitations (up to 3 researchers in one location, use of face masks and other appropriate PPE, screening prior to in-person activities) and adhere to any local regulations that may provide additional limitations. Plans for field work should be reviewed by college leadership and the VPRI in advance, particularly if the field work requires travel outside of the Milwaukee region. Community-based research activities involving human research participants should follow the guidelines above.

Animal Resource Center
• Animal breeding and ordering will be permitted if ARC personnel are sufficient in number and supplies are available. The timing of additional research activities involving the ARC will also require consideration of the move into the renovated facility. Additional guidance will be provided when Stage 3 work commences.
• Additional in-person animal research activities where physical distancing may be maintained, or risk mitigated to a minimal risk level, may take place. Animal research activities (i.e., experiments or surgeries) will need to be reviewed by the Department Chair and coordinated with ARC Management to ensure compliance with all safety and social distancing guidelines.

MU-RR Stage 4: Return to Steady State Operations with On-going COVID-19 Protections
Stage 4 represents a return to steady state operations with, however, on-going COVID-19 Protections. The VPRI will, in consultation with the University’s COVID-19 Response Team, determine the timeframe for transition to Stage 4. This timeline will be determined following an evaluation of the level of strict adherence to the requirements of prior stages, current public health status, and the University’s capacity to support the increased level of activity.

General Laboratory Guidelines
Stage 4 for returning to work in the research laboratories of Marquette University will be guided by the following principles. These may be adapted prior to, or during, implementation based upon best public health practices and University policy.
• Research will be conducted in University offices and laboratory facilities. Remote work practices will follow normal University policies.
• Research meetings, including laboratory meetings, will continue to be conducted within the facilities, complying with University restrictions on meeting size (if any).
• Individuals uncomfortable with working on-site must work with their faculty supervisors and Department Chair to resolve conflicts on workplace safety.
Anyone entering the facility must complete a self-assessment checking for viral symptoms prior to starting work.
  - Individuals developing viral symptoms while at work must leave the facility immediately.
- Physical distancing measures remain to be determined, but some elements of social distancing might be required.
- Face masks might be required.
- Consistent and regular handwashing is expected.
- Laboratories will be fully staffed
- Laboratory workspace, keyboards, etc. must be wiped down by the worker with 70% ethanol or similar antimicrobial solution prior to commencing work, and after finishing work.

Work with Human Research Participants

Safety precautions outlined in Stage 3 continue to be in place and general laboratory guidance for Stage 4 is followed.

Field Work and Community-Based Research Activities

Safety precautions outlined in Stage 3 continue to be in place and general laboratory guidance for Stage 4 is followed.

Animal Resource Center

Restarting to return to full animal research operations. The return to the new normal protocols may be gradual and, in some cases, it may require additional sub-phases, which can be defined under guidance of Department Chair, ARC Management, and the VPRI.

Appendices

Appendix A     Previous Lab Ramp-Down Guidance
Appendix B     Research Ramping Request Form
Appendix B     Alternative Form: Research Ramping Request
Appendix C     Animal Resource Center Plan
Appendix D     PPE Recommendations for Research Activities Involving Human Participants (revised)
Appendix E     Sample Screening Tool for Research Involving Human Participants
Appendix F     Consolidated Department or College Level Plan for Stage 2 Increased Activities
Appendix G     SOP for Research with Human Participants
Appendix H     COVID-19 Risk Information Sheet for Participants