

Standard Operating Procedures: Guidelines for Human Subject Research

These guidelines for standard operation procedures (SOP) for human subject research in response to COVID-19 are consistent with the Marquette University [Recovery Plan](#) and [Ramping Research plan](#). The expectation is that all research personnel will adhere to the following principles while conducting research with human subjects either on or off campus.

A. Relevant Guiding Principles

Principle #1: Recommendations and guidelines which mitigate risk of the spread of infection must adhere to local government and public health directives when working with human participants. See the [Marquette University Recovery Plan](#) for specifics.

- **Physical distancing** means at least 6 feet of distance between individuals within research space and office areas. This may require work schedules that are staggered in time and space, and possibly coordination with all participating laboratory groups when research space is shared.
- **Face masks will be worn in all public areas such as hallways and restrooms and will be required in research spaces when interacting with other researchers and human participants.** General mask usage will follow University Recovery Recommendations. More specific recommendations for personal protective equipment (PPE) for work is provided toward the end of this document (Table 1).
- **Consistent and regular handwashing** is expected.

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. This includes activities such as research team meetings.
- **Daily screening of all researchers and research participants returning to campus** will follow the University's Recovery Plan.
- **Any researcher who needs to self-quarantine** due to COVID-19 diagnosis, symptoms, exposure or other reasons is asked to complete Marquette's voluntary self-disclosure form <https://www.marquette.edu/coronavirus/covid-19-employee-and-student-voluntary-disclosure.php>.
- **Research activity is voluntary:** Because some individuals may not be comfortable with on-site work, participation in research activities is voluntary during initial phases of research ramp-up. Students and other trainees are particularly vulnerable and must not be made to feel that participation is required.
- **Cleaning:** Shared laboratory workspace, keyboards, etc. must be wiped down by the individual research personnel with 70% ethanol or similar approved disinfection solution

prior to commencing work, and after finishing work. Facilities Planning and Management (FPM) will provide cleaning materials and guidance for proper usage in laboratory and other non-public spaces not maintained by FPM personnel.

- **Training of research personnel:** Faculty/Principal Investigators (PIs) are responsible for educating and training research personnel and regular monitoring of compliance with University guidelines related to COVID-19. Faculty will provide a list of research 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.
- **Planning for resurgence:** 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.

B. Laboratory Guidance

1) Research Activities to be Conducted Remotely

- 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 remote.
- Research meetings, including laboratory meetings, will continue to be conducted online from remote locations.

2) For On-Campus (non-remote) Research

- **Screening:** Anyone entering the research facility must complete the University's screening process prior to starting work each day. Research personnel will report that they have successfully screened to their PIs, and PIs will report to their chair or designated supervisor.
- **Development of COVID-19 symptoms:** Individuals developing COVID-19 symptoms while at work must leave the facility immediately and follow Marquette's guidance (Principle 2).
- **Physical distancing measures, wearing face masks, and frequent handwashing** must be strictly maintained (see Guiding Principle 1). Personnel in the laboratory and research space must wear a face mask while with others including research personnel and participants (unless this is deemed unsafe by the faculty).
- **People per room:** Please refer to the Marquette University [Ramping Research plan](#) for guidance regarding number of people per research space as these guidelines are dependent on Stage of ramping up process.

- **Faculty supervision:** It is expected that faculty or other designated research supervisors will be on campus regularly to ensure compliance with SOP.
- **Non-Marquette University employees** who are collaborators must comply with the SOP guidelines when conducting research on Marquette campus.
- **Research activity is voluntary:** Because some research personnel including students may not be comfortable with on-site work, participation in research activities continues to be voluntary during this phase. Students and other trainees are particularly vulnerable and must not be made to feel that participation is required.
- **Safety Plan:** An approved safety plan, including check-in process (buddy-system) must be in place and followed in any case where only one person is present at a time in a research room. This is normally expected as part of laboratory safety protocols.
- **Cleaning:** Laboratory workspace sanitization protocols must be strictly followed (see Guiding Principle 2 in the introductory materials above).
- **Training:** All research personnel will be educated and trained (overseen by the PI) to ensure compliance with the standard operation procedures (see Guiding Principle 2).
- **Foot traffic and pathways:** Research personnel will adhere to approved foot traffic paths to reach research facilities, and restrooms and other common areas used by laboratory/research personnel.

C. Research with Human Participants on Marquette Campus

IRB-approved research activities for research involving human participants approved for face-to-face research, will meet the following guidelines:

- **Studies where physical distancing can be maintained.** One-to-one meetings between a researcher and participant in which strict distancing measures are met can be conducted and include maintaining 6 feet distance and the use of face masks.
- **Studies that do not allow for physical distancing must have an approved PPE plan and availability.** Guidance for PPE is shown in Table 1 of this document (Appendix D for the Marquette Ramping Research Plan).
- **Numbers of people in the laboratory/research space:** In general, the guidelines established in the Ramping Research plan regarding the number of personnel within research spaces must be strictly followed. PI's can request a deviation from these guidelines, via the Research Ramping Request Form (Appendix B of Ramping Research Plan), in cases where such a change is needed to ensure the safety of research participants.

- **Screening procedures of personal and participants must be strictly adhered to when engaging in face-to-face meetings.** An example screening guide is found in Appendix E.
- **Protocols with participants considered at high-risk** (vulnerable) should take extra precautions when establishing study procedures and using proper PPE to mitigate, as much as possible, the risk of exposure. The Marquette COVID-19 medical team is available for consultation on an as needed basis. Refer to [CDC guidelines for who is considered a high-risk participant](https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/people-at-higher-risk-old.html): <https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/people-at-higher-risk-old.html>

Screening Procedures

Prior to participant arrival: Screening process for human research participants include pre-check via phone call (or other medium) per *COVID-19 Human Research Participant checklist* to consider all factors when determining appropriateness for research participation.

On arrival: When meeting and interacting with a participant, the following procedures are suggested if determined appropriate to participate in research study:

1. Before entering research space and participating in research activities, participants will be provided a mask if they do not have their own. Participants will be asked to bring their own, if possible, to preserve PPE.
2. Upon immediate entry of research space (if not prior), temperature of participant should be taken before participating in research activities (limit visit to participant only, unless caretakers/caregivers are needed).
3. Research participation will not be allowed if:
 1. temperature **at or above 100.4° F**, or
 2. Checking for any respiratory symptoms (cough, sneeze, difficulty breathing, etc.),
or
 3. The participant reports exposure to persons with COVID-19.
4. Participant will be asked to wash hands or sanitize hands upon entry into research space.

Flagged Participant (Participant Does Not Meet Entry Criteria)

- A participant that does not pass the screening on arrival must be sent home immediately and may not come back for participation for *at least 14 days*, quarantining at home and asymptomatic throughout that time period.
- Participants that are flagged during the screening prior to arrival may not participate for *at least 14 days*, quarantining at home and asymptomatic throughout that time period.
- Researcher(s) who encountered a flagged participant must also go home immediately, and not come back to perform research, quarantining at home and asymptomatic in accordance with university guidelines prior to resuming research. The researcher is advised to fill out Marquette [online COVID-19 exposure survey](#).

D. Facility / Laboratory

- **Cleaning:** Research personnel must thoroughly clean and sanitize all equipment and rooms used before and after each use and/or period of occupancy. Shared workspace, keyboards, etc. must be wiped down by the worker with 70% ethanol or other approved disinfectant prior to commencing work, and after finishing work.
 - The PI involved with the research project is responsible for ensuring that cleaning and sanitizing procedures are followed before and after arrival of the participant.
 - Facilities Planning and Maintenance (FPM) will provide cleaning materials and guidance for proper usage in laboratory/research spaces and other non-public spaces not maintained by FPM personnel.
- **Log of Room and Equipment Use:** It is recommended that researchers (overseen by the PI) maintain a log of all rooms and equipment used during each session to ensure extra facilities cleaning needs are met and for contact tracing as needed.

E. Research with Human Participants off Campus (non-Marquette sites), in the Field and Community

Field work and community-based research activities involving human research participants should follow the human research participants guidance above.

Research that is conducted at off-campus sites should follow the guidance and requirements of those sites. MU personnel will obtain guidance and requirements of non-Marquette sites and provide to other members conducting research at the site. Researchers should, at the very least, adhere to the Marquette SOP guidelines while conducting research off campus and be prepared to include any additional constraints or procedures imposed by the host organization. Off-campus research may not allow for as much coordination as on-campus research, so an abundance of caution must be applied, including proper consideration of travel limitations, shared equipment and space use, and reduced risk of infection for both participant and researcher.

In the case where the guidelines are not clear in the off-campus site to help mitigate the rate of infection of COVID-19, the researchers should follow the guiding principles in this SOP document.

F. Personal Protection Equipment Requirements

(Donning/Doffing Protocols and Minimal Protection Requirements)

- **PPE minimal protection requirements** will generally follow those provided in Table 1 below (Appendix D of the University-wide research ramp-up plan).
- **All researchers must be trained in properly donning/doffing PPE** prior to assisting with research. The PI associated with the research project is responsible for ensuring that all research staff are trained and proficient in minimizing contamination and viral exposure when donning/doffing PPE. See links below.
 - Donning PPE: <https://www.youtube.com/watch?v=H4jQUBAlBrI>
 - Doffing PPE: <https://www.youtube.com/watch?v=PQxOc13DxvQ>
 - An additional instructional video with donning and doffing in the same video can be found [here](#).

Table 1: Guidelines for PPE Research Activity	Researcher PPE	Participant PPE
Physical Distancing (> 6 ft) with <i>Minimal</i> Aerosolization and Fluid Exposure (e.g. in-person interview)	Level 1 (or greater) Mask Gloves* Eye glasses, goggles, or face-shield highly recommended but not required	Level 1 (or greater) Mask Eye glasses, goggles, or face-shield highly recommended but not required
Physical Distancing (> 6 ft) with Aerosolization and Fluid Exposure	N95 Mask Gloves* Goggles or face-shield	Level 1 (or greater) Mask Eye glasses, goggles, or face-shield highly recommended but not required
Close Proximity (< 6 ft) with <i>Minimal</i> Aerosolization and Fluid Exposure (e.g. DXA scan)	Level 1 (or greater) Mask Gloves* Eye glasses, goggles, or face-shield as needed	Level 1 (or greater) Mask Eye glasses, goggles, or face-shield highly recommended but not required
Close Proximity (< 6 ft) with Aerosolization and Fluid Exposure	N95 Mask Gloves* Goggles or face-shield, Cap, and Gown	Level 1 (or greater) Mask Eye glasses, goggles, or face-shield highly recommended but not required
Participants Cannot Wear PPE Mask for research participation (e.g. aerobic capacity test)	N95 Mask Gloves* Goggles or face-shield, Cap, and Gown as needed	Eye glasses, goggles, or face-shield highly recommended but not required
Invasive Procedures with Fluid Exposure but <i>Minimal</i> Aerosolization (e.g. biopsy, blood draw)	N95 Mask Gloves* Goggles or face-shield, cap, and Gown as needed	Eye glasses, goggles, or face-shield highly recommended but not required

*Use of gloves is protocol-dependent (may not be required in all cases).

Mask reuse for researchers are to be accordance with [CDC guidelines](#).

All users are to be knowledgeable in donning (putting on) and doffing (taking off) masks and other PPE.

Donning PPE: <https://www.youtube.com/watch?v=H4jQUBAIBrl>

Doffing PPE: <https://www.youtube.com/watch?v=PQxOc13DxvQ>

An additional instructional video with donning and doffing in the same video can be found [here](#).