

Marquette University Human Subjects Research PPE Guidelines

Purpose: To provide clear guidance on the appropriate use of personal protective equipment (PPE) for human subjects research, with the goal of minimizing risk to subjects and researchers and mitigate the spread of COVID-19

*Recommendations meet or exceed current CDC and state guidelines and **assume both researcher and participant have been screened to be asymptomatic upon arrival.** Study-specific protocols regarding the use of PPE should be based on the following recommendations and must be approved prior to implementation as specified in the Ramping Research Plan.*

Implementation:

- PPE that must be worn for the entire research session is *based on the most stringent requirements for activities that will occur during that session*
 - The research session is defined as the time from first entering the research space until last leaving the space
- Cloth masks fall into the minimal to low performance category and should not be used in a research setting
 - Participants arriving with a cloth mask should be provided a mask prior to entering the research space
- Perform thorough handwashing before donning and after doffing all PPE, and immediately upon entering the research space
 - All research spaces must have a designated “safe zone” for donning/doffing PPE
- Take care to avoid touching the mask, except when donning/doffing
 - If touching a mask without gloves, perform thorough handwashing immediately
- Masks and/or PPE must be discarded immediately if damaged or significantly soiled
 - Move to a safe distance away from all others before doffing damaged PPE and donning new gear
- Reused masks should be stored in a clear plastic bag or clean paper bag and labeled with the user’s name (see [CDC guidelines](#))

Mask Levels:

| | |
|--|----------------|
| MAXIMUM FILTRATION | N95 |
| NIOSH Approved N95 Particulate Respirator High Fluid Resistance 160 mmHg Filtration Efficiency PFE = 99.9% @ 0.1 micron Breathability - Delta P > 5.0 mm H ₂ O/cm ² Flame Spread Class 1 | |
| ASTM LEVEL 3 | LEVEL 3 |
| High Fluid Resistance 160 mmHg Filtration Efficiency BFE ≥ 98% PFE ≥ 98% @ 0.1 micron Breathability - Delta P < 5.0 mm H ₂ O/cm ² Flame Spread Class 1 | |
| ASTM LEVEL 2 | LEVEL 2 |
| Moderate Fluid Resistance 120 mmHg Filtration Efficiency BFE ≥ 98% PFE ≥ 98% @ 0.1 micron Breathability - Delta P < 5.0 mm H ₂ O/cm ² Flame Spread Class 1 | |
| ASTM LEVEL 1 | LEVEL 1 |
| Low Fluid Resistance 80 mmHg Filtration Efficiency BFE ≥ 95% PFE ≥ 95% @ 0.1 micron Breathability - Delta P < 4.0 mm H ₂ O/cm ² Flame Spread Class 1 | |
| LOW PERFORMANCE | |
| Surgical Molded Utility Mask Physical Barrier Only No LEVEL Performance Level ** Filtration Efficiency N/A | |
| ** Unless mask manufacturer certifies that the mask meets LEVEL performance Level 1 | |
| MINIMUM PERFORMANCE | |
| Utility Mask (Tissue/Tissue) Physical Barrier Only No LEVEL Performance Level Filtration Efficiency N/A | |

| 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.

Here are video links by the CDC on how to [don](#) and [doff](#) PPE. If you cannot access the above links, cut and paste the following web addresses directly into your web browser

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

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

An additional instructional video about donning and doffing PPE in the same video can be found [here](#).
<https://www.youtube.com/watch?v=twE8UtwndeQ&feature=youtu.be>