

UWM Human Subjects Face-to-Face Research Guidelines Fall 2020

- Human subjects research is now subject to the following color-coded levels:

Red	Data analysis, remote/virtual data collection, and other activities not requiring direct interaction with subjects.
Orange	Face-to-face interactions with low-risk populations in the same room that maintain social distance (greater than 6 ft.) or which require close (within 6 ft.) <u>or</u> direct contact for a limited duration (< 15 minutes).
Yellow	Face-to-face interactions with low-risk populations involving more extensive close or direct contact.
Green	No restrictions on human subjects research.

- Face-to-face testing of higher-risk populations is not allowed until Level Green is declared.** Study teams are responsible for reviewing the [CDC’s information on higher-risk populations](#) and to identify whether their subject population or any individual subject is at higher risk.
- Permissible activities for levels Orange and Yellow Levels include IRB-approved protocols and pilot/feasibility studies that (1) align with the priorities noted under “General Considerations” in the [Fall 2020 Research Reopening Plan](#), (2) follow UWM’s guidelines for face-to-face human subjects research (detailed below), and (3) have an approved [Research Operations Safety Plan](#).
- All human subjects activities that can be done remotely should be done remotely, including consenting. Submit an amendment to the IRB to allow for remote consenting and study procedures, if these are not already in your approved protocol.
- Room and building density constraints may limit permissible face-to-face research activities (see [Fall 2020 Research Reopening Plan](#), section B.1).
- The contact area and duration of any physical contact with participants should be reduced to the minimum necessary to accomplish the activity. Additional risk mitigation methods described in the UWM Emergency Operations Center (EOC) guidelines should be used, such as use of face masks, gloves, and face shields if their use is appropriate to the respective scenario, and supplies should be sanitized prior to and after contact with participants (detailed guidance below).
- All activities to prevent the spread of COVID-19 are public safety activities and thus must follow all EOC guidance. As such, these are not study-specific research activities and DO NOT need to be reviewed by the IRB. This applies to the requirements related to social distancing, sanitization, personal protective equipment, and other precautions outlined in the rest of this document.
 - **Changes to your research activities require IRB review and approval.** Examples include:
 - Requesting approval to waive signed informed consent (remote consenting).
 - Modifying in-person activities so they can be conducted virtually.
 - Eliminating or modifying activities that require close contact with individuals, such as drawing blood.
 - Changing eligibility criteria to exclude individuals considered to be high risk due to the pandemic.
 - For more information: <https://uwm.edu/irb/covid-19-guidance/>

Federal, state, and UWM guidelines can change quickly, and thus the EOC recommends that study teams frequently review the UWM Office of Research’s [COVID-19 web page](#) for the most recent guidance on PPE and controls for direct contact with study participants.

- Required face-to-face safety plan components:
 1. Cleaning Protocol – List all affected surfaces to be disinfected
 2. Testing Protocol
 - a. PPE (Researcher and participant requirements)
 - b. Pre-visit screening (e.g., COVID, study eligibility, informed consent)
 - c. Pre-arrival setup (e.g., leave door open, pre-position materials for participant)
 - d. Testing protocol (e.g., Researcher will wear mask and face shield/goggles when in close contact)
 3. Post-testing protocol (e.g., participant exit plan, equipment cleaning)

Guidance for Minimizing COVID-19 Risks for Face-to-Face Research Activities

Preparation and Planning

The best protection from person-to-person transmission of COVID-19 is to minimize in-person interactions. Before resuming face-to-face activities with human subjects, consider whether study procedures can be altered to reduce the number or duration of required in-person interactions.

When preparing the workspace where face-to-face research activities will take place, study teams must consider the risks of the space and the best method(s) to mitigate those risks. To maximize the effectiveness of these safety measures, advance planning and practice for study activities is important prior to restarting work.

Step 1: Physical Distancing

When in-person interactions are unavoidable, physical distancing whenever possible is the most effective means to reduce the spread of COVID-19. When planning your research activities, there are several ways to maximize physical distancing between individuals in the study workspace:

1. Observe and follow any site-specific rules regarding physical distancing practices, including established room and building density constraints.
2. Use tables and chairs to create seating/work areas that are at least six feet apart from each other.
3. Create a one-way flow of traffic for participants:
 - a. Use signs, arrows, and lines to direct participants (note that UWM discourages indelible markings on floors).
 - b. Create a pathway using furniture or physical barriers (e.g., cones, ribbon, rope).
 - c. Create workstations using markings, signs, chairs, tables, etc.
 - d. Provide supplies (paper, pens, forms) for study team participants in convenient locations in the traffic flow.
4. Reduce movement in the study workspace to help maintain distancing for study team members:
 - a. Establish individual work areas and tasks in advance.
 - b. Set up workspace and supplies in convenient areas for use.
5. Communicate
 - a. Discuss in advance with team members how the distancing measures will work.
 - b. Practice traffic flow and workstation processes with study team members. This will help identify areas where additional measures may be needed.
6. At any point where physical distancing is not possible, additional protective measures, such as additional PPE, will be needed.

Example: A study team member must check the pulse of a participant's wrist during an interview. The team member can maintain distancing as long as feasible during the interview. In order to take the pulse, it may be recommended that the study team and participant wear additional face coverings and use hand sanitizer before and after the pulse is taken and before touching other items.

Step 2: Hand Hygiene

Study team members and participants must frequently wash their hands or clean hands with sanitizer.

1. To ensure proper hand hygiene, you must have at least one of the following options available:
 - A handwashing sink with soap, disposable towels, and waste container.
 - Ensure a clear path to and from the sink is available to maintain physical distancing.
 - Alcohol-based hand sanitizer (at least 60% alcohol content).
 - Place sanitizer in multiple locations to encourage use and minimize movement in study area.

2. Hand hygiene should be performed frequently throughout a study team session. When in doubt, wash/cleanse your hands. Best practices include:
 - Before study activities begin and after all activities end.
 - Between different study participants.
 - Before handing an item to or before making contact with a participant.
 - Before touching face, mask, face shield, respirator, or eye protection.
 - After handling an item from a participant.
 - After contact with high-touch surfaces, such as an equipment keypad, doorknob, phone, chair, or tabletop.
 - After removing any PPE (e.g., mask, eye protection, face shield, respirator, smock, gloves).
 - Before and after coughing, sneezing, blowing nose, and handling personal items.
3. Hand hygiene can be minimized by avoiding direct contact or direct exchange of items with participants or fellow study team members:
 - Set out office supplies in advance where they will be needed (e.g., pens, paper forms, clipboards)
 - Place items on a table instead of handing to/from another person.
 - Attach paper forms to a clipboard if multiple people must use the form. The clipboard can be handled and cleaned easily.
 - Place chairs, tables, and other equipment in areas of use to reduce the need to move them in the study workspace.
4. Proper respiratory hygiene
 - Cover coughs, sneezes, and nose-blowing with tissue, clothing, and/or hands. Wash/cleanse hands immediately afterwards.
 - Encourage participants to do the same.
 - Provide tissues, hand sanitizer and disposal in convenient locations.

Step 3: Personal Protective Equipment (PPE)

Face coverings are required for study team members and participants when conducting face-to-face research activities. Depending on the research activities, study teams may use additional PPE.

PPE descriptions:

- Face covering (cloth mask, surgical mask).
- Eye protection (safety glasses, face shield, safety goggles).
- Respiratory protection (N95 or other respirator).
- Gloves (vinyl, nitrile, latex gloves).
- Clothing protection (cloth or paper/disposable smock, lab coat, gown).

When physical distancing cannot be maintained, additional PPE should be worn by study team members to increase protection against droplet contamination or for individual health concerns.

1. Eye protection is recommended when research activities will be conducted at a close distance.
2. Gloves may be useful if study team members must make physical contact with a participant's skin or facial area.
3. Clothing protection may be useful when research activities will be at close distance for prolonged periods and/or with multiple participants over prolonged periods.

4. N95 or other respiratory protection is NOT recommended for face coverings for these reasons:
 - a. Respirators must be fit-tested to properly function as respiratory protection and are ineffective if worn without proper fit-testing to the individual user.
 - b. Respiratory protection is appropriate only if the face-to-face interaction is with an individual with known or suspected COVID-19, or when specimens from an individual with known or suspected COVID-19 must be manipulated outside of a containment device (e.g., biosafety cabinet).
 - c. N95 respirators are in short supply.
5. Face shields do not replace the use of a mask as a face covering. Face shields provide a broader facial barrier and may be more comfortable to wear than goggles or safety glasses as eye-protection, but do not provide the same close nose-mouth barrier as a mask.

Step 4: Evaluate Surfaces and Equipment to be Disinfected

Identify high-touch surfaces and frequently used equipment items that will require disinfection. Have disinfection solutions, disposable wipes, gloves and a disposal container available. See [CDC Cleaning & Disinfecting Guidance](#) for Communities and [EPA-Approved Disinfectants for SARS-CoV-2](#).

1. High-touch surfaces, including:
 - a. Door handles, chair back, workstation tabletop.
 - b. Phone, keyboard, mouse.
 - c. Equipment touchpads, handles, knobs.
 - d. Pens, clipboards.
 - e. Any items shared by more than one person in the workspace.
2. Hard, non-porous surfaces can be effectively disinfected as needed.
3. Soft, porous materials (e.g., wood, fabric) are difficult to disinfect. If this will be a high-touch surface, it must be disinfected in some manner. Options include:
 - a. Avoid using these types of items in the study area, or
 - b. Prepare the item so it can be disinfected (e.g., plastic covering over a cloth chair to be wiped clean), or
 - c. Prepare the item so it can be kept from contamination (e.g., paper covering over cloth chair that can be disposed between users).
4. Equipment may be sensitive to repeated disinfection:
 - a. Plastic covers may be placed over high-touch areas and repeatedly disinfected.
5. Provide disinfectant materials where they will be needed in the study workspace in advance of study activities:
 - a. Choose appropriate disinfectant and follow the label instructions for dilution and use.
 - b. Obtain a supply of disposable wipes for disinfection use.
 - c. Place disinfectant and wipes in areas of use to reduce the need for study team members to move around and possibly break physical distancing.
6. Disinfecting surfaces:
 - a. Wear gloves.
 - b. If possible, clean the surface with soap and water prior to disinfection.
 - c. Use the appropriate disinfectant and disposable wipes.
 - d. Wet the surface with disinfectant, thoroughly spreading the disinfectant across the full surface using the wipe. Do not dry the surface with the wipe.

- e. Dispose of the wipe.
- f. Allow the surface to remain wet with disinfectant for the appropriate contact time for the disinfectant (Table 1).
- g. After contact time is completed, the surface is disinfected and can be used. If surface is wet, a disposable wipe may be used to dry the surface.

Table 1. Disinfecting Materials and Use

Disinfectant Product	Minimum Contact Time	Notes
Lysol Disinfecting Wipes	10 minutes	Ensure lid is closed between uses to prevent wipes from drying out.
Clorox Disinfecting Wipes	4 minutes	Ensure lid is closed between uses to prevent wipes from drying out.
Cavi-wipes	3 minutes	Ensure lid is closed in between uses to prevent wipes from drying out.
70% Isopropyl alcohol 70% Ethanol	5 minutes	Do not apply directly to equipment; moisten cloth or paper towel to wipe equipment. Evaporates quickly and may not remain wet for full contact time.

7. Disinfecting surfaces when visible contaminants are present:
 - a. Use the appropriate disinfectant and disposable wipes.
 - b. Cover the contaminated area with a clean or disinfectant-dampened wipe(s).
 - c. Saturate the wipe with disinfectant.
 - d. Using another wipe, carefully pick up the saturated wipe(s) and dispose.
 - e. If the contaminant material is still present, repeat this procedure until the surface is visibly clean.
 - f. Saturate the surface again with disinfectant, thoroughly spreading the disinfectant across the full surface using a wipe. Do not dry the surface with the wipe.
 - g. Allow the surface to remain wet with disinfectant for the appropriate contact time.
 - h. After contact time is completed, the surface is disinfected and can be used. If surface is wet, a disposable wipe may be used to dry the surface.

Step 5: Disposal

Place disposal receptacles in locations where they are likely to be used in the study workspace. Study items must be disposed properly to minimize risks and comply with regulations regarding medical wastes. The facility where you conduct work also may have specific disposal procedures, which you are obligated to follow. If you are in a laboratory, clinical, or healthcare facility, ask for the facility disposal procedures.

Outside of a lab, clinic, or healthcare facility, follow these disposal best practices:

1. Dispose as regular trash:
 - Office supplies (e.g., unwanted paper, posters, signs, Post-Its).
 - Used paper towels from handwashing.
 - Used tissues.
 - Non-medical supplies not contaminated with blood or body fluids:
 - Unused, unwanted cotton swabs, gauze pads.
 - Trash/wrappers from opened packets of medical supplies.
 - NEVER dispose needles, lancets, razor blades, or scalpels in the regular trash, even if they are unused and/or unopened.

2. Dispose in a medical Sharps Container:
 - Used needles, lancets, scalpels, razor blades.
 - Scissors, forceps, tweezers which will not be decontaminated for re-use.
 - Glass slides, pipets, and pipet tips are allowed in Sharps Containers but not required.
 - Excess/unwanted clean needles, lancets, scalpels, razor blades (even if they are still in the package).
 - Medical Sharps Containers must be disposed as medical waste and not placed in the trash.
 - UWM Sharps disposal guidance <https://uwm.edu/safety-health/biosafety-disposal/>
3. Dispose in a biohazard bag/container:
 - Disposable items (masks, gloves, bandages, gauze, swabs, paper/plastic table covers) contaminated with blood or body fluid.
 - Durable items contaminated with blood or body fluids that cannot or will not be disinfected for re-use (e.g., broken goggles contaminated with blood).
 - Used wipes from disinfection steps where visible contamination was cleaned from an area.

PPE that is not visibly contaminated with blood or other body fluids is not considered biohazardous and thus may be disposed in the regular trash. However, be aware that a facility may have special rules regarding PPE disposal into their trash containers.

Step 6: Safely Performing Face-to-Face Research Activities

On the day(s) when activities will be conducted with study participants, include the following safety steps in your activities:

1. Wash/cleanse hands using alcohol-based hand sanitizer.
2. Prepare the workspace to set up traffic flow, workstations, work areas, disposal locations and PPE, as determined in the preparation steps.
3. Wear the PPE needed for the workspace.
4. Clean work surfaces and equipment with disinfectant prior to beginning work:
 - a. Wear gloves when cleaning and disinfecting.
 - b. Use plastic to cover soft surfaces that may be high-touch areas and cannot be disinfected.
5. Remove gloves and wash/cleanse hands after disinfection steps.
6. When conducting research activities with study participants:
 - a. Wash/cleanse hands frequently:
 - Between participants.
 - Before and after making physical contact with participants.
 - After handling items given to you from participants.
 - After disinfecting an area.
 - After disposing of research items or PPE.
 - b. When possible:
 - Avoid handling items directly from participants.
 - Avoid handing items to participants.
 - Encourage participants to cleanse hands before/after the session and additional times as desired.

7. When concluding research activity:
 - a. Wash/cleanse hands frequently and avoid touching face or personal items until study space and materials have been disinfected.
 - b. Collect any disposable supplies/items and discard:
 - Office supplies, paper forms, signs, posters, tape, etc. that can be disposed in regular trash.
 - Medical or lab supplies must be disposed in biohazard waste bags.
 - Needles, lancets and other medical sharps must be disposed in a Sharps Container.
 - c. Collect any reusable supplies and disinfect surfaces prior to putting away.
 - d. Disinfect work surfaces, including equipment and all areas of contact in the study workspace.
 - e. Collect disposal bags/containers if needed from facility for proper disposal.