UNC ESHELMAN SCHOOL OF PHARMACY

Guidelines for Conducting Safe Human Subjects Research for Investigators and Study Teams within the UNC Eshelman School of Pharmacy

[adapted from the UNC School of Medicine Office of Research and the Clinical Research Support Office (CRSO) Guidelines: https://www.med.unc.edu/crso/in-person-activities/som-guidelines-and-processes/)

GOAL: Workspace occupancy ≤50% of normal with a 6ft distance between individuals (e.g., no more than 1 person/200 sq. ft.). If you cannot maintain a 6ft distance, please include plans for the appropriate personal protective equipment that your researchers will wear.

For human subjects research that cannot be conducted virtually, each PI is required to prepare a plan for their research personnel and workspace, and send it to their Chair/Center Director with a copy to the Associate Dean for Research for review and approval prior to beginning human subjects research. Elements of that plan should include:

1. Documentation of approval provided by either the School of Medicine (SOM) or School of Pharmacy Clinical Research Review Committee (see page 6).
2. Full names of researchers, position (e.g., staff, trainee), and hours they are scheduled to work.
3. Number of personnel in workspace during shift versus total number of research personnel (not just your personnel but others occupying the same workspace). Discuss with supervisor of space.
4. Location and dimensions of workspace (see drawing as an example) with general personnel locations, equipment, desks, and location of research patient/participant(s) in chair or bed.
5. Personal safety practices that you will have in place for your researchers and participants (include plans regarding safety, hygiene, cleaning, and disinfection of surfaces, etc.).
6. Plans for training your research personnel regarding safety issues. COVID-19 safety training is available for all UNC employees (https://apps.fo.unc.edu/ehs/training/protecting-the-carolina-community-from-covid-19/). Upon successful completion of the post-test, the employee will receive email documentation of completed training.
7. By submitting this plan, the PI confirms that s/he has reviewed and carefully considered the expected benefits versus risks for study participants (previously enrolled or to be enrolled) and believes that the study should continue with in-person contact visits/assessments in the context of COVID-19. The PI should include the following statement at the beginning of the plan:
   "I understand and accept my responsibility as PI, including additional responsibilities in the context of COVID as detailed below:
   - **Prior to initiating in-person human subjects research work as described in the plan, all study personnel (faculty and staff) will receive appropriate training on required COVID-related workflows designed to ensure workplace safety, worker safety and participant safety including wellness checks, masking, social distancing, work shifts, cleaning protocols, participant screening and triage. I accept personal responsibility to ensure that these workflows are followed.**
   - **Study participants will be provided information regarding the current COVID-19 epidemic and how best to reduce their risk of infection. Study personnel will discuss with all research participants the anticipated benefits and risks of attending in-person study visits in the context of COVID-19. Each participant will be given ample opportunity to make an informed decision about participating in face-to-face visits.**
   - **All research participants will be screened for COVID symptoms using UNCH criteria by research staff prior to the research visit if possible, with repeat screening by research staff at the time of an in-person visit before being cleared to participate in an in-person research visit. If a participant has fever or other symptoms of potential COVID-19 infection, they will be instructed not to come for in-person study visits and should only come to UNC Health campus if they need clinical care.**

   If the risk/benefit profile for study participants related to COVID-19 changes for any reason (study-related or related to changes in UNC Health recommendations), I understand it is my responsibility to re-assess and carefully consider any new circumstances to determine whether contact with study participants should continue."

In addition to the guidelines provided by the Office of the Vice Chancellor for Research (https://research.unc.edu/covid-19/resuming/all/) and (https://research.unc.edu/covid-19/resuming/human-subjects/), the following guidelines are provided to PIs conducting human subjects research. PIs are responsible for ensuring the safety of their staff, trainees, and patients. Each PI must use their best judgement, and consult with the Division Chair or Center Director if they have specific questions or concerns.

General Guidelines

- **W**ear a mask, **W**ash your hands, **W**ipe what you touch, **W**ellness check before coming to work.
- Researchers who can effectively conduct their work remotely should continue to work remotely so as not to place themselves or others at unnecessary risk.
- Study team meetings, smaller research/writing working group meetings, and journal clubs should continue to occur via Zoom.
- Whenever possible, communication should occur via Zoom, WhatsApp, text, email, Microsoft TEAMS or other non-personal contact methods.
- Individuals who have been instructed to return to on-site work and wish to request a disability accommodation (e.g., for disabilities that place individuals at higher risk for severe illness from COVID-19) should contact the Equal Opportunity and Compliance Office at eoc@unc.edu.
- The University will provide guidance separately on requests for workplace flexibility for other situations, such as individuals who are at higher risk due to age or other factors, as set forth under CDC guidelines, or individuals who live with those who are high-risk.
- Personnel on campus will be provided masks (1-2 per week), hand sanitizer, disinfectant, and gloves (if needed) by UNC, as outlined in separate guidelines. Masks for study subjects must be provided by the research investigators.
- Guests of employees, visiting trainees, and other persons not affiliated with UNC (including children of employees) should not visit University facilities or offices.
- Compliance with required practices is a shared community responsibility (see pages 7-8).

Wellness Check and Symptom Monitoring

Each employee must check for symptoms before coming to work. As outlined by the CDC (https://www.cdc.gov/coronavirus/2019-ncov/symptoms-testing/symptoms.html), employees must NOT COME TO WORK (or leave work immediately) if they have (or develop) any of the following symptoms:

1. **New muscle aches** not related to another medical condition or another specific activity (e.g., due to physical exercise)
2. A **temperature of greater than 100.0°F or chills**
3. **Sore throat** not related to another medical condition (e.g., allergies)
4. **New or worsening cough** that is not related to another medical condition
5. **Shortness of breath or difficulty breathing** not attributable to another medical condition
6. **Recent (<5 days) loss of smell and taste**
7. New onset of **vomiting or diarrhea** not related to another medical condition
8. **Recent close contact with someone who has tested positive for COVID-19**

Personnel exhibiting COVID-19 symptoms should contact their health care provider, and act upon their instructions. Their supervisor should be notified. UNC employees may contact the University Employee Occupational Health Clinic (919–966–9119), and UNC students and postdoctoral fellows may contact UNC Campus Health (919–966–2281). Any individual who has tested positive for COVID-19, who has been referred for testing, or who is awaiting test results, **may not come to work on campus for any reason until approved to do so** by Employee Occupational Health or Campus Health.

Personal Protective Equipment (PPE)

While in a University facility, all individuals must wear a University-approved face mask https://carolinatogether.unc.edu/returning-to-the-work/) when in the presence of others and in public settings, including conference rooms, classrooms, and common spaces.

Face Masks: **The University will provide disposable face masks to employees and trainees.**

- Masks, hand sanitizer and other cleaning supplies are being distributed regularly to research personnel by the School's FAO team. Details can be found on the School's COVID-19 webpage.
- Each person working on campus will be provided one disposable face mask for use every two shifts, or every two days of work. If an individual's work duties require more frequent disposal and replacement of masks, those needs will be accommodated.
- Disposable face masks are not meant to be laundered. Persons using such masks must not touch their face after removing the mask and must wash their hands for at least 20 seconds with soap and warm water after removing the mask.
- Please utilize a personal mask when coming and going to campus, and utilize a work mask when arriving to the research facility. Make sure to follow the steps in this video (https://www.youtube.com/watch?v=Ypj_1pFD1kA&feature=youtu.be) to ensure you wear your mask correctly. Do not remove the mask when going to the restroom (as indicated in the video). Pay attention to guidance on how long each mask should last and how to store it properly between wearings.

Eye Protection: UNC Health's Universal Pandemic Precautions is a safe, sustainable practice that protects you from exposure to unknown COVID+ cases and includes:

- Everyone wears an earloop mask when able (research participants, patients, visitors, vendors, and all UNC Health staff and providers).
- When a participant is not able to mask, staff must wear eye protection [a face shield, a face mask with attached face shield, or safety goggles or glasses that offer wrap around protection to the side of the eyes (see poster)] in addition to their own mask.
- Eye protection does not include standard prescription glasses (even with side shields) or contact lenses.
- Eye protection should be disinfected and reused:
    - Wipe with an EPA registered hospital disinfectant and let dry.
    - Rinse with water or alcohol if residue remains.
    - Replace if broken or no longer able to be cleaned.

Gloves: According to the CDC, gloves are not necessary for general use and do not replace good hand hygiene. Frequent hand washing (at least 20 seconds with soap and warm water) is considered the best practice for common everyday tasks. Employees who will be interacting with the public or operating in a public setting where materials will be frequently exchanged are advised to wear disposable gloves. The University will provide gloves for these individuals. Instructions for how to remove and dispose of gloves properly is available at the UNC Environment Health & Safety website (https://ehs.unc.edu/infectious-diseases/coronavirus/ choose "Community Protective Equipment").

Hygiene and Cleaning

Hand Washing

- Hands should be washed often with soap and warm water for at least 20 seconds.
- Hands should be washed before interacting with a research participant and immediately after the session is over.
- Please view the CDC's "Five Steps to Wash Your Hands the Right Way" (https://www.cdc.gov/handwashing/when-how-handwashing.html).
- Also, please view the CDC Video on Handwashing (https://www.cdc.gov/handwashing/videos.html).
- Provide research participants the opportunity to wash hands if they are visiting you in your facility.
- If hand washing is not an available option, use hand sanitizer to disinfect hands.
- All individuals should thoroughly wash their hands or use provided hand sanitizer:
  - At least hourly.
  - Before entering or exiting buildings, laboratories, or offices if they have been in a public space or near others.
  - Before and after handling their facemask.

Cleaning and Sanitizing

- Human subjects research may involve the frequent use of shared equipment. The University is increasing the cleaning frequency of common/public spaces; however, it is critical that all faculty, staff, and students share the responsibility of cleaning and sanitizing high-touch surfaces in their workspaces (e.g., light switches, doorknobs).
- Cleaning products and hand sanitizer are provided by UNC for this purpose (see above).
- Occupants of all workspaces should clean/wipe all high-touch surfaces when beginning work, at the end of the day, and at least four additional times daily.
- Shared equipment should be cleaned and wiped after each use.

General Information Related to Human Subjects Research During COVID-19

Reopening of human subjects research in UNC facilities is dependent on (1) approval from the Office of the Vice Chancellor for Research (OVCR) to resume human subjects research activities involving in-person participant contact, and (2) the following:

- University policy allowing non-essential employees back on campus.
- Availability of PPE so that healthcare workers have adequate PPE and investigators and research participants have a mask at all face-to-face interactions.
- Individuals follow the COVID-19 prevention rules of UNC Health and the medical director of the facility in which patient/participant-facing activities are occurring.

Pertinent information relevant to human subjects research may be found at the following links:

- COVID-19 Information: https://www.unchealthcare.org/coronavirus/
- OVCR: https://research.unc.edu/covid-19/
- OHRE: https://research.unc.edu/2020/03/10/ohre-irb-covid-19-update/
- School of Medicine Clinical Research Support Office (CRSO): https://www.med.unc.edu/crso/
- Travel and Parking: Travel for UNC business is currently not permitted outside of the state at this time. The University will release more information about travel when we receive further guidelines from the UNC System and the State (https://carolinatogether.unc.edu/travel-event-guidelines/). Information on changes to University parking policies and public transit can be found at the University Transportation & Parking website (https://move.unc.edu/).

Non-interventional human subject research studies that do not include participant contact

- These IRB-approved studies that do not include participant contact can continue (e.g., population health studies that utilize EHR data). If the work is conducted in UNC facilities, the PI is responsible for ensuring that all the guidance herein is adhered to with respect to workplace safety and social distancing, as detailed above.

Non-interventional, observational, or interventional human subjects research studies that include participant interactions and can be completed virtually

- These IRB-approved studies can continue (i.e., interviews conducted remotely). If the work is conducted in UNC facilities, the PI is responsible for ensuring that all the guidance herein is adhered to with respect to workplace safety and social distancing, as detailed above.

Observational or interventional studies that include in-person participant contact (in clinical or non-clinical spaces)

- Studies that require face-to-face assessments or visits can continue, weighing risks and benefits for the participants. If the potential benefit of a face-to-face visit for a research participant exceeds the risk, visits are desirable (e.g., a patient who is doing well in a trial needs a blood test to monitor renal function or drug concentrations to be able to continue the study product safely). If, in the PI's judgement, the potential benefit of the visit and continuation of the trial product exceeds the potential risk of the visit, the visit is allowed. The CDC (https://www.cdc.gov) recognizes nine high-risk groups for severe outcomes with COVID-19 such as those over age 65. As part of the ongoing consent process, research participants at high risk for severe outcomes should only be asked to participate if there are clear benefits to patients. They should understand the risks of breaking social distancing. Regardless of the location of the face-to-face visit (clinical vs. non-clinical space), participants and research personnel must undergo the same screening procedures, and follow the same mask and visitor policies as detailed elsewhere in this document.

Specific Procedures and Guidelines for Research Studies Involving In-Person Patient/Participant Contact

The following is a list of required procedures for conducting human subjects research visits that involve in-person contact with study participants. More details are available at https://research.unc.edu/covid-19/resuming/human-subjects/ based on the OVCR's May 23, 2020 communication (https://research.unc.edu/covid-19/resuming/) and the Clinical Research Support Office (CRSO)'s response page (https://www.med.unc.edu/crso/in-person-activities/unc-health-guidelines-related-to-covid-19/).

- Consider the following measures to reduce direct contact, as applicable: drive through service where available for blood draw only visits rather than participant coming into the clinic/research site, use drive-by visits or mail to supply research participants with study medication/materials and use remote or virtual visits when possible.
- Prior to a face-to-face visit, research personnel must perform telephone wellness screenings and confirm the participant's appointment no more than 24 hours prior to the scheduled visit. Research personnel that have Epic access must document the completed screening in Epic for any research visits that occur at any UNC Health facility. For studies occurring in non-clinical spaces or for studies that do not utilize Epic, record of the participant wellness screening should be appropriately documented in the study records. For patient, companion, and employee screenings in clinics not located at the UNC Medical Center, refer to the document "UNC Medical Center Outpatient Clinic Screening at the Door" workflow document (https://www.med.unc.edu/crso/files/2020/06/UNC-Medical-Center-Outpatient-Clinic-Screening-002.pdf).
- Research personnel will be subject to daily wellness checks prior to entering any UNC Health/School of Medicine clinical research facility. A colored dot that changes daily will be placed on everyone's shirt/badge to outwardly demonstrate that they have been screened. Those individuals found to be positive for symptoms consistent with COVID-19 will immediately leave the work environment (not enter the facility) and be advised to contact Occupational Health. Employees should recognize symptoms in advance and not report to the workplace if unwell. If study staff will be conducting visits in non-clinical spaces, the wellness check must be performed by another responsible party (e.g., supervisor) prior to initiating a study visit.

- Research personnel must follow UNC Health's Mask policy regarding proper usage and storage of masks for employees (https://www.med.unc.edu/crso/in-person-activities/unc-health-guidelines-related-to-covid-19/#Employee_Mask_Policy), and masks for participants (https://www.med.unc.edu/crso/files/2020/05/Universal-Mask-Policy.pdf).
- Wear goggles or a face shield if a research participant cannot wear a face mask reliably.
- Research personnel must be aware of and follow UNC Health's COVID-19 Visitor policy (https://www.med.unc.edu/crso/files/2020/05/COVID-19-Workflow-Visitation-Implementation-Plan.pdf) to determine who is permitted to attend visits with participants; all visitors must complete a prescreening wellness check prior to and on arrival to the clinic or designated research visit location.
- Participants will be rescreened upon arrival to a UNC Health facility by front desk staff. Research personnel must rescreen participants upon arrival for visits that will occur in non-clinical spaces before the visit begins (no symptoms, as detailed above) and appropriately document the screening in the study records. Any participant who fails rescreening should be immediately masked and isolated in a private room. Clinical study personnel should be contacted and follow recommendations from Infection Prevention regarding referral for testing. The UNC patient COVID-19 Helpline number is 888-850-2684.

Process to initiate human subjects research involving in-person patient/participant contact:

- The study PI must review and carefully consider the expected benefits vs. risks for study participants to determine if the study should continue with in-person contact visits or assessments (continued participation or recruitment) during the COVID-19 pandemic. If the PI determines the study should continue, the **PI must complete a COVID-19 Study Information Form,** including his/her attestation to the expected benefit/risk assessment.
    - **If the PI or co-PI is a School of Medicine faculty member, or if research activities involving in-person contact with participants will take place in School of Medicine space (e.g., CTRC) regardless of the PI/co-PI School affiliation, complete this form:** (https://reports.tracs.unc.edu/surveys/?s=W7TF39MTFP).
    - **If the PI is a School of Pharmacy faculty member and conducting in-person participant contact at a location on or off campus other than in School of Medicine space**, contact the School of Pharmacy Office of Research and Graduate Education (arlob@email.unc.edu) for the study information form.
    - The PI's Department/Division Chair/Administering Unit must review and recommend that the request be approved or declined according to the risk assessment.
    - Forms approved by the Chair/Administering Unit will be reviewed by a School of Medicine or School of Pharmacy Clinical Research Review Committee. This committee will make the final decision regarding whether or not the study can resume during the COVID-19 pandemic, and will notify the PI of the decision.
- As part of the ongoing consent process, the participant should also understand the potential harms of visiting a health care facility at this time and agree willingly to the visit. For example, the risk to a frail elder with a history of cancer and heart disease may be greater by coming to a study visit than the potential benefit from the care provided in the context of the study. Each participant should be given the chance to discuss the expected risks and benefits and make an informed decision regarding participation, along with support from the study team.
- All studies that have been allowed to continue study activities due to direct benefit, or have been given permission by the School of Medicine or School of Pharmacy to resume activities in alignment with the OVCR's updated guidance, will be **required to provide a COVID Information Sheet for UNC and External Sites to subjects** (unless enrollment is due to a COVID diagnosis and treatment), that outlines the risk of COVID-19 and the risk mitigation strategy that has been outlined. The **COVID Information Sheet for UNC and External Sties** may be accessed from the Office of Human Research Ethics (OHRE) website (https://research.unc.edu/human-research-ethics/consent-forms/). This is an information sheet only and does not need to be signed, however

the conversation with participant's, the risk analysis for subject continuation, and the outcome of the discussion should be documented in the subject's research record using this template (https://www.med.unc.edu/crso/files/2020/06/COVID-19-Participant-Discussion-Documentation-Template.docx).

- Provided that the consent template is used verbatim, except where "X's" have been inserted to allow for study specific information, then the use of this template does not need to be submitted to the IRB for approval. Please retain a copy of the "COVID Information Sheet Approval Letter" (https://research.unc.edu/2020/05/26/ohre-irb-covid-19-update-2/; see Related Materials at bottom of page) in your study files. ***If you would like to make changes to this information sheet, outside the "X's" for general information, either to add, remove language, or if your procedures for risk mitigation are different, this requires the submission of a modification including a risk analysis to the IRB.*** You may not begin activities until those changes have been submitted, reviewed, and approved by the IRB. If you were previously given permission by the OVCR's office as your study provided direct benefit, you may continue, however the COVID information sheet above should be used until the modified language is approved, if alteration of language is necessary.
- This information sheet is institution-wide and reflects UNC's guidance and OVCR's institutional policy. This information sheet, or another approved by the UNC-IRB should be used for all research being conducted by UNC-Chapel Hill regardless of the IRB of record. If you have questions about this please reach out to John Roberts (jtr@unc.edu), the Associate Director of Regulatory Affairs and Compliance.

General guidelines for research studies involving in-person patient/participant contact:
Use this checklist (https://www.med.unc.edu/crso/files/2020/06/Participant-Visit-Checklist-COVID-19.docx**) to ensure you are considering all applicable guidelines prior to conducting a face-to-face visit with a research participant.**

- All materials used during study visits should be appropriately cleaned and sanitized before and after each study visit (e.g., chairs, surfaces, exam tables, clipboards, pens, blood pressure cuffs, exercise equipment)
- Practice good hand hygiene before and after each patient encounter and before preparing a room for a research participant encounter (as always!):
  - Wash hands often with soap and warm water for at least 20 seconds
  - If soap and water are not readily available, use an alcohol-based hand sanitizer that contains at least 60% alcohol.
- Increase the frequency of cleaning and disinfecting, **focusing on high-touch surfaces.**

General Guidelines for Worker Safety

- **PIs should carefully prioritize research activities that are most important to resume, and carefully consider which personnel will complete these activities.** While some personnel will be eager to resume work, others may be reluctant. PIs should assure that research personnel being assigned responsibility for research activities are willing to follow the guidelines.
- **Encourage personnel to stagger break times to minimize contact between people**. Seating in workspaces must be at least 6 ft apart in all directions.
  - Whenever possible, eat before or after work, or eat outside to avoid eating in the lab/building. Shorter shifts may facilitate maximizing work efficiency with minimal down-time.
  - Break rooms, microwaves, and common eating areas should be avoided whenever possible.
  - Disinfect surfaces such as tables and chairs before and after use.
  - Cups, mugs, plates, and silverware must be washed with soap before and after use.
  - Wash your hands before and after using a break room.

  https://www.cdc.gov/coronavirus/2019-ncov/prevent-getting-sick/cleaning-disinfection.html

- **Whenever possible, each researcher should have their own set of frequently used tools** (please label with your name or initials) such as notebooks and writing instruments.
- **Gloves and disposable towels should be used when handling common items, shared equipment, common computers, and cabinet handles.**
- **Door handles should be wiped or sprayed with 70% ethanol** (or other EPA approved disinfectant) frequently. Ideally, post a log sheet to document daily disinfection.
- **Increase the frequency of cleaning and disinfecting, focusing on high-touch surfaces.**
- **Use the stairs whenever possible.** Use of elevators is subject to the required physical distancing guidance.
- **Clean and disinfect affected surfaces as soon as possible after a known exposure to a person with respiratory symptoms (such as coughing/sneezing).**

Create a plan for shared equipment.

- **All shared equipment must be disinfected *before* and *after* each use.**
- **Wear disposable gloves while cleaning and disinfecting.** Discard gloves after each use. Clean hands immediately after gloves are removed.
- **Disinfect equipment that normally makes direct physical contact with human skin**, which includes eyepieces for microscopes, keyboards, touch pads, freezer door handles, etc.
- **Use disposable tissues, paper towels, Kimwipes, etc. to touch surfaces that cannot be disinfected and when gloves are not available.**
- **Use disposable towels to turn off sink faucets and open doors after hand washing** to avoid re-contaminating hands.
- **Consult manufacturer recommendations on cleaning products appropriate for electronics.** If no guidance is available, consider the use of alcohol-based wipes or spray containing at least 70% alcohol. Use of alcohol-based products may reduce risk of damage to sensitive machine components. Whenever possible, consider using wipeable covers for electronics.

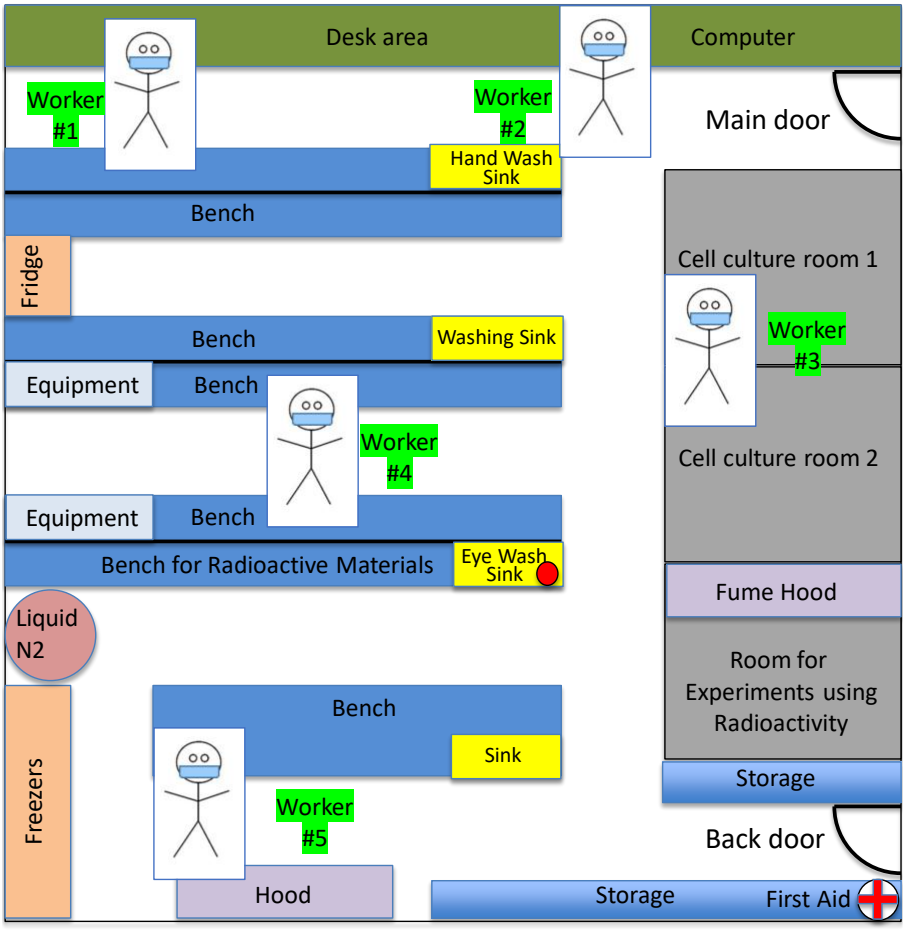
Create a plan for interactions with others outside the research environment.

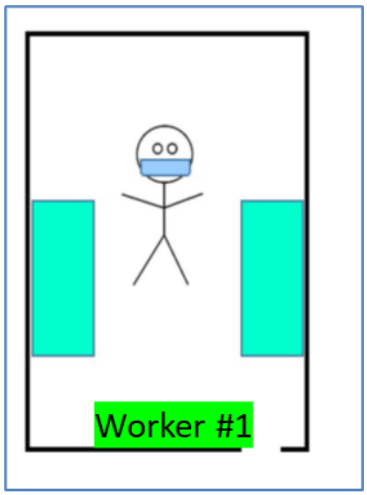
- **Do not congregate in entrances, hallways, stairwells, or elevator lobbies.**
- **Contact with other research groups should preferably be through phone calls or email/text messaging** except in cases of extreme emergency.
- **Transfer of items should be arranged by leaving them in a designated area** rather than handing them over in person.
- **Use of shared facilities and other researchers' equipment should be pre-arranged** in order to avoid accidental contact.
- **Assembling or convening in groups of greater than 10 people poses a significant risk of viral transmission and is not permitted.**

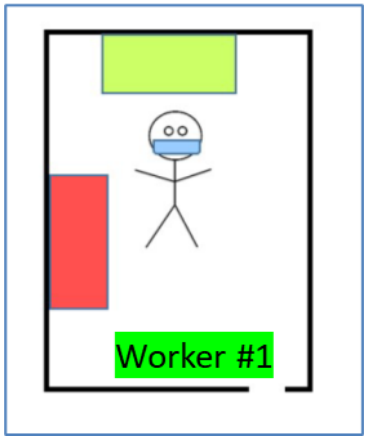
Plans for monitoring compliance.

- **Compliance with these guidelines is critical to keep everyone safe and back at work.** Each PI must discuss with all of their research personnel the importance of compliance.
- **Peer-to-peer monitoring is encouraged**: "if you see something, say something." To report violations of compliance rules: (1) politely ask the person to please comply, and (2) if the person refuses to comply, please report this to your PI designate, PI and/or anonymously through the Carolina Ethics Line at 866-294-8688.
- **Each PI should consider designating at least one individual (e.g., senior research member) who will oversee compliance issues/concerns** and report problems to the PI, Chair/Center Director, and/or Associate Dean for Research.
- **Please submit questions or comments, or suggest ideas for implementation or share best practices here**: **"Campus Reopening Questions, Concerns and Suggestions" form.**

The following maps serve as a guideline only for spacing of lab personnel in laboratory and work rooms. Please draw your own maps and tailor them to your own workspaces and distribute to your research personnel.







- Guidelines are to keep at least 6 feet distance between 2 people, and everyone wears a mask
- Work in shifts, if needed, so that not all personnel are in the workspace at the same time (consider using an online calendar for scheduling work times).
- Each room should have no more than 1 person with a mask per every 200 sq. ft., or 1 person per bay, depending on room configuration. Avoid working directly across from each other.
- Room capacity: 1 person per 150-250 sq. ft. office, cold room, equipment room, tissue/cell culture room, or BSL2 room.
- Equipment in close proximity should be moved to allow more than 1 person at a time to use equipment.
- Clean all common areas, equipment, and surfaces after each use.