PHASE I RAMP UP OF RESEARCH

GUIDELINES FOR THE CLINICAL PROGRAM IN THE DEPARTMENT OF PSYCHOLOGY AND NEUROSCIENCE

CREATED ON 5.27.20
BRIEF STATUS UPDATE: RESEARCH ACTIVITY ON THE UNC CAMPUS

STATUS and PROCESS for the RAMP-UP

- Initial Phase of Ramp-Up will begin June 1 with goal of increasing operations to 50% of on-site capacity.
- During this phase, all research that can be performed remotely should continue to be done so.
- Plans for how to ramp up research are coordinated through the Office for the Vice Chancellor for Research (OVCR) who will approve departmental plans.

What research activities are allowed?

- During phase I, research on campus will no longer be restricted to specifically approved “critical research activities,” and the forms for that purpose will no longer need to be submitted to the OVCR.
- Studies that have not been previously approved as “critical research activities” but that involve human subjects research will be subject to the direction and guidance for conducting human subjects research issued by the OVCR (see slides to follow).
WHAT THESE GUIDELINES COVER

- An overview of COVID-19
- LAB MANAGEMENT including the use of campus research spaces (regardless of whether data collection is occurring in those spaces)
- HUMAN SUBJECTS RESEARCH with a focus on in-person data collection occurring on campus
- FIELD-BASED RESEARCH that involves in-person data collection at off-campus sites

The following guidelines are informed by materials provided by the OVCR, OHRE, SOM, and other areas within the Department of Psychology and Neuroscience. These guidelines do not include procedures to ramp-up activities in the Community Clinic, a training clinic in which some research activities occur. For research activities that occur within the structure of the Community training clinic, guidelines for all three areas (lab management, human subjects research and field-based research) should be followed. As guidelines for the clinic become available, they should be followed as part of conducting research through the clinic as well.
PART ONE: ABOUT COVID-19

- Per OSHA, “Coronavirus Disease 2019 (COVID-19) is a respiratory disease caused by the SARS-CoV-2 virus.”

- Over 1.7 million people in the United States have been confirmed to have COVID-19, with over 5 million cases worldwide, as of May 26, 2020.

- Symptoms include fever, cough and shortness of breath and may appear 2-14 days after exposure. Some individuals are asymptomatic, with no symptoms being displayed at all.

- Routes of exposure include close contact between people, when respiratory droplets are produced from an infected person when they cough or sneeze and inhaled by nearby individuals.

- In order to reduce the virus from spreading, tactics such as social distancing, increasing hand hygiene and education are being encouraged.

Photo courtesy of Hannah A Bullock; Azaibi Tamin; CDC: PHIL ID #23354
SYMPTOMS OF COVID-19

A wide range of symptoms have been reported, from asymptomatic to severe. The more common symptoms may include:

- Cough
- Shortness of breath or difficulty breathing
- Fever
- Chills
- Muscle pain
- Sore throat
- New loss of taste or smell

*This is not a list of all possible symptoms. Others, such as gastrointestinal distress, have been reported. Contact your medical provider for more information and treatment options.

Emergency Warning Signs* – seek immediate medical treatment

- Trouble breathing
- Persistent pain or pressure in the chest
- New confusion
- Inability to wake or stay awake
- Bluish lips or face

*This is not a list of all possible symptoms. Contact your medical provider for any symptom that is troubling you or are severe.

Call ahead to your local emergency facility or 911 to inform them that you suspect COVID-19.

Check the CDC website for more information:
If you suspect or know that you have been exposed to COVID-19, take the following actions:

- Stay home. Do not leave your home, except to receive medical treatment. Do not go to public places.
  - Self-quarantine for 14 days, after known exposure, travel to an outbreak area, displaying symptoms or positive test for COVID-19.
  - Notify your supervisor immediately.
- Rest and stay hydrated. Take over-the-counter medicine, such as acetaminophen, to help you feel better.
- Stay in touch with your medical provider and call ahead before appointments.
- Monitor your symptoms. If you have trouble breathing or other severe symptoms, seek medical attention.
- Avoid ride-sharing and public transportation.
- Isolate yourself away from others within your home.
- Dispose of tissues and wash hands frequently.
- Clean all commonly used surfaces and avoid sharing items with household members.

If you travel out of state, once you return to NC you must self-quarantine for 14-days before returning to the lab. This is a requirement.

Other Resources for students, faculty and staff:
- UNC Student Health - https://campushealth.unc.edu/
- UNC Hospital (with anonymous symptom checker) - https://www.unchealthcare.org/coronavirus/
PART TWO: LAB MANAGEMENT

Guidelines for lab management and using campus lab spaces during Phase I address the following issues:

- Workplace Expectations and Symptom Monitoring
- Physical Distancing in Lab Settings
- Standard Safety Requirements
- Scheduling and Occupancy Limits
- Lab cleaning Requirements
WORKSPACE EXPECTATIONS AND SYMPTOM MONITORING

- Individuals who can effectively work from home should continue to do so.
- 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.
- It is our understanding that UNC will provide guidance on workplace flexibility for those at risk for other issues (e.g., due to age, living with high-risk individuals or other issues). We recommend that anyone who has a concern with returning to the office discuss the issue with their supervisor.
- Anyone returning to work should confirm each day that they have no COVID-19 symptoms (see prior slide: new muscle aches, temperature greater than 100, unexplained sore throat or cough, shortness of breath, loss of smell or taste, unexplained vomiting or diarrhea, shaking chills). A daily wellness checklist follows this slide. Those with symptoms should not come to campus and should contact a health care professional.
- Anyone testing positive for COVID-19 must not return to campus until approved by the Employee Occupational Health or Campus Health offices.
WORKSPACE EXPECTATIONS AND SYMPTOM MONITORING

- No visitors should be permitted in workspaces.
- Consider posting room occupancy on doors of shared meeting spaces.
- Masks should be worn in common rooms and walkways as well as labs.
- Researchers should have access to their own set of tools (e.g., pens, notebooks, staplers)
- Elevators should be avoided when possible and otherwise limited to one occupant.
- Distance thermometers will be placed at entrances for those entering the building. Anyone using these thermometers will clean them and store them for everyone’s use.
DAILY EMPLOYEE PRE-SHIFT WELLNESS CHECKS

In an effort to protect the safety and well-being of employees, providers, participants, and the community at large; all employees/providers should conduct a wellness check prior to the start of every shift. How this wellness check occurs will be up to individual labs. Those individuals found to be positive for symptoms consistent with COVID-19 will either not report to or will immediately leave the work environment (not enter the facility) and be advised to contact Occupational Health at 919-966-9119.

- Employees whose work is solely performed in a university managed building (e.g. labs) – the wellness check must be performed by another responsible party (e.g. supervisor) or by self-reporting via an online system prior to reporting to work.
- Employees who perform work in any UNC Health facility – all research personnel entering any UNC Health facility will be subject to daily wellness checks prior to entering. UNC Health uses a colored dot system, which changes daily, and will be placed on everyone’s shirt/badge to outwardly demonstrate they have been screened.
- Employees who will be conducting visits in non-clinical spaces (e.g. Mary Ellen Jones) – the wellness check must be performed by another responsible party (e.g. supervisor or PI) prior to initiating a study visit.

The employee wellness check should include the following questions (subject to change or be expanded as needed based on current CDC guidelines):

- Do you have new muscle aches not related to another medical condition or another specific activity (e.g. due to physical exercise)? (If so, take temperature)
- Do you feel like you may have a temperature of greater than 100.0°F? (If so, take temperature)
- Do you have sore throat not related to another medical condition (e.g. allergies)?
- Do you have a new or worsening cough that is not related to another medical condition?
- Do you have shortness of breath that is not attributable to another medical condition?
- Do you have recent (<5 days) loss of smell and taste?
- Do you have new onset of vomiting or diarrhea not related to another medical condition?
- Do you have repeated shaking chills not related to another medical condition?
PHYSICAL DISTANCING

- Limit individuals within the laboratory space
  - Encourage working remotely when possible
  - Continue virtual gatherings for lab meetings and discussions requiring several lab members
- Individuals should always wear lab appropriate PPE while in the lab. At a minimum this includes a cloth mask or paper mask, but certain labs may require additional PPE.
  - Individuals that are classified as high risk, such as immunocompromised, should have appropriate accommodations for their well-being and protection. This may include coming in when no one else is in the lab, wearing N95 masks, or avoiding the lab altogether.
- Eliminate multiple entries into a space to control traffic flow through the lab.
PHYSICAL DISTANCING

- Remove excess chairs to encourage social distancing.
- Maintain at least 6’ distance between work stations.
- There is a limit of one person per 200 cubic feet of space. This may mean that some spaces can accommodate no more than one person at a time.
- While physical distancing and hygiene are important, so is exposure time of individuals working in the same space for extended periods of time.
- In general, the best practice is for one person working in a room at any given time.
- Use tape or floor decals to provide visual cues to maintain physical distancing.
PERSONNEL AND TIME MANAGEMENT

- Implement shifted schedules to limit individuals working in the lab to 50% or less.
  - This can be done in a variety of ways: including set times, team shifts, specific days, etc.
  - Consider using an open access calendar, such as Google Calendar, to track workflow in the lab.
- Stagger arrival/departure times by at least 30 minutes to reduce traffic.
- Avoid working alone during late hours and consider a “virtual buddy system” in case you need assistance.
PERSONNEL AND TIME MANAGEMENT

- Instruct individuals to use Google Calendars to reserve equipment or computer access as needed.
- Individuals that sign up to use equipment (including shared computer stations) will be responsible for sanitizing the equipment before and after each use.

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COMMON PROGRAM SPACES

- When possible, individuals should work in their own labs and avoid shared spaces.
- Maintain proper mask and PPE guidelines when working in common spaces.
- Encourage eating meals/taking breaks away from the lab and discourage using group/open office plans.
Plans for how to regularly sanitize shared lab areas (including table tops) should be implemented by each lab.

Recommended practices include:

- Using Sign-off logs to verify regular disinfecting procedures are followed.
- Spraying surfaces with CDC-recommended sanitizing solutions
- Use 70% alcohol solution on door key codes/alarm pads, to prevent long term deterioration of the soft rubber components.
- 70% alcohol wipes may also be used to clean surfaces and may be best for instruments including computers
- Shipped supplies and boxes that come in should also be disinfected.
- Commercial disinfectants approved by the EPA can be found here: https://www.epa.gov/pesticide-registration/list-n-disinfectants-use-against-sars-cov-2
Each lab should issue mask guidelines and equipment.

- Cloth masks are a minimum standard for all labs, though some lab activities may require other PPE.
- It is recommended to wear cloth masks in common/public areas where social distancing is not an option.
- Cloth masks are typically made of multiple layers of fabric and can be washed for reusability.
- Masks should fit flush against the side of face, covering the nose and mouth.
- For more information on the CDC’s advice on cloth masks, visit: https://www.cdc.gov/coronavirus/2019-ncov/prevent-getting-sick/diy-cloth-face-coverings.html

- Dust/Paper Masks may be used in the laboratory, along with other proper PPE for lab work.
- Cloth masks should be removed upon entering the lab and replaced with a dust/paper mask.
- Dust/Paper masks can be reused if not soiled, contaminated or damaged.
- An individual can store a used paper mask inside a clean paper bag with name and stored until next use. Do not seal the bag.
- Replace the dust/paper mask every three days of use. These mask types cannot be washed.

- N95 Masks are designed for front-line employees, health care workers and lab members who have a high risk for exposure to contaminants.
- N95 masks are reusable and designed to block 95% of particles at the .3 micron level.
- Users must complete training with EHS and be fit tested before using them.
- More information on UNC’s EHS N95 program can be found here: https://ehs.unc.edu/workplace-safety/rpp/
REDUCING EXPOSURE - MASKS

- Carefully remove the mask, utilizing the elastic.
- Do not touch the front of the mask or your face during or after removal!
- Wash your hands with soap and water for at least 20 seconds after removing and storing your mask.
REDUCING EXPOSURE – HYGIENE

- Follow good handwashing procedures – 20 seconds of soap and warm water upon entering the lab, between glove changes and before leaving the lab.
- Cover any coughs or sneezes with tissue. Immediately wash your hands afterwards.
- Use hand sanitizer with at least 60% alcohol content if soap and water are not available.

www.cdc.gov/handwashing
PART TWO: DIRECTION AND GUIDANCE FOR CONDUCTING HUMAN SUBJECTS RESEARCH

KEY PHASE I OVCR DIRECTIVES:

- Human subject research studies that do not include direct participant contact may continue.
- Human subject research studies that include participant interactions and can be completed virtually should be conducted virtually provided the IRB has approved the virtual/remote interaction for a particular study.
- All other studies that require in-person contact must adhere to a departmental approval process and take into consideration the following guidelines for altering research protocols.
What type of in-person data collection efforts may resume?

- Studies that require face-to-face assessments or visits may continue depending on how they weigh risks and benefits for the participants. Risks and benefits may not be the same for all groups in a study and additional exclusion criteria may be needed. The argument for resuming activities will be reviewed by the department along with proposed protocol changes.
- Note that the CDC recognizes high-risk groups for severe outcomes with COVID-19. These include those aged 65+, living in a nursing home or long-term care facility, or those with certain underlying medication conditions (particularly if not well controlled).
- Changes in protocols to reduce risk should prioritize remote or virtual data collection, drive-by procedures (that do not require entering campus buildings), and outside data collection.
- The department will consider the following OVCR guidelines in evaluating research protocols for studies with in-person data collection wishing to resume activities. Note that PIs may choose not to resume activities or to seek departmental approval if they believe the risks outweigh the benefits at any time.
- Research that involves participants of 10 or fewer individuals in a group, such as a focus group, is allowed. Seating should be arranged to allow 6 feet between group members, and all focus group participants must wear masks.
HUMAN SUBJECT STUDIES THAT REQUIRE PARTICIPANT CONTACT SHOULD ADHERE TO THE FOLLOWING GUIDELINES

Consent Procedures

- As part of the ongoing consent process, research participants, especially those at high risk for severe negative outcomes, should understand the risks of breaking physical distancing. The OHRE/IRB has provided an informational sheet to provide to participants for this purpose. Use of this form does not require permission (an IRB modification) to your protocol.

- Prior to visiting campus (or meeting with research personnel in-person at a non-campus location), research personnel should explain potential harms of visiting the research site during the COVID-19 pandemic and actively confirm that participants agree willingly to the visit. This consent procedure should include participants receiving information about the expected risks and benefits of the research, including those of visiting the research location, and having the opportunity to discuss their concerns with the research team (consistent with best practices for informed consent). Remote consent is encouraged if approval has been granted by the IRB. (For additional UNC Health Guidance on COVID-19, please visit the Clinical Research Support Office (CRSO)’s response page.

- Decision charts for how to use consent procedures and whether IRB review is required are included in the next two slides.
# Consent Processes-IRB

Please refer to "Consenting Study Subjects in Isolation and Documentation " slides;

Please remember some of this is dependent upon the risk level of the study (minimal risk/greater than minimal risk) and if its FDA regulated.

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<td>Clearly outline how this is within current research question</td>
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Letter from OHRE regarding approval to use COVID Information Sheet
HUMAN SUBJECT STUDIES THAT REQUIRE PARTICIPANT CONTACT SHOULD ADHERE TO THE FOLLOWING SAFETY GUIDELINES

Safety Procedures

- Prior to a face-to-face visit, research personnel must confirm the participant’s appointment and perform telephone wellness screenings no more than 24 hours prior to the scheduled visit, if applicable.

- Participants visiting a campus location must be rescreened by research staff at the front door of the building upon arrival (i.e., confirm there are no symptoms, no fever, etc.) and conduct a temperature scan. Any participant who fails rescreening should be asked to leave the building and may be rescheduled after symptoms abate or they are tested and determined to be COVID-19 free. Recommendations from Infection Prevention regarding referral for testing should be followed. The UNC Health guidelines for screening participants follows this slide.

- During face-to-face visits, research personnel should maintain a physical distance of 6 feet whenever possible, wear face-masks, and wash hands before and after face-to-face interaction with a human research participant.

- Interactions should take place in an outdoor setting, if possible.

- All lab management practices should be built into study protocols, including the use of masks and other PPE determined necessary for the specific protocol, lab cleaning, physical distancing, and scheduling of space and equipment.
HUMAN SUBJECT STUDIES THAT REQUIRE PARTICIPANT CONTACT SHOULD ADHERE TO THE FOLLOWING SAFETY GUIDELINES

Safety Procedures

- When a participant is not able to mask, staff must wear eye protection in addition to their own mask (e.g., 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). Standard prescription glasses are not eye protection. All eye protection equipment should be disinfected after use.

- Gloves are at the discretion of the project but handwashing is best practice and is a minimum standard.

- Anyone accompanying someone to a testing session should be asked to remain outside of the building.

- Additional safety procedures may be needed for studies of children and other vulnerable populations.
PARTICIPANT VISIT SCREENINGS

The below screening questions should be asked for all participants and companions. Any participant who screens positive should be referred to the UNC Health COVID-19 HelpLine at 1-888-850-2684 for additional screening and further instructions:

- Do you feel feverish or do you have a fever?
- Do you have a new or worsening cough?
- Do you have a new or worsening sore throat?
- Are you newly short of breath?
- Have you had a loss of taste or smell in the last 5 days?
- Do you have new onset vomiting or diarrhea?
- Do you have new onset of repeated shaking with chills not related to another medical condition?

Participants and companions will be re-screened upon arrival to a UNC Health facility by Front Desk staff. Research personnel must re-screen participants and companions upon arrival for visits that will occur in non-clinical spaces before the visit begins (e.g. no symptoms, no fever) and appropriately document the re-screening in the study records. Participants and companions should also receive a temperature scan upon arrival to the clinic or research site. Any participant who fails re-screening should be immediately masked and isolated in a private room, and clinical study personnel (e.g. PI) should be contacted and follow recommendations from Infection Prevention regarding referral for testing. Companions who fail re-screening should be immediately asked to leave the facility and to contact their primary care provider or other appropriate medical facility for further evaluation and testing.
PART IV: DIRECTION AND GUIDANCE FOR CONDUCTING FIELD-BASED RESEARCH

- Field-based and community-based participatory research may continue if permitted by the University and by the School’s Research Dean and if the required safety measures in the OVCR guidance can be followed.

- When interacting with individuals in the field, University-provided masks should always be worn, and gloves should be used if directly interacting with or exchanging items with another individual. Researchers must provide masks and gloves (if direct interaction or exchange of items is required) for study subjects.

- In the field, physical distancing (minimum 6 feet distance while wearing a mask) is required and outside venues are preferred whenever possible.

- Researchers must adhere to all safety guidelines provided by the research site, including but not limited to, use of additional protective personal equipment, if required.

- If research participants are provided data collection equipment (e.g., wearable devices) for use in the field site, that equipment must be thoroughly cleaned and sanitized prior to release to and following return from each participant’s use. Cleaning supplies and directions for using those supplies with the data collection equipment, must be provided to participants for their own use.
PART IV: DIRECTION AND GUIDANCE FOR CONDUCTING FIELD-BASED RESEARCH

- If research involves travel or overnights, accommodation and meals should allow for adequate physical distancing (6 feet or more) wherever feasible. Vehicle occupancy should be limited to two people in a standard car, with open windows while travelling if possible. Vehicle occupants should wear masks.

- Travel for UNC business is currently restricted to North Carolina and is not permitted outside of the state at this time. The University will release more information about travel when it receives further guidelines from the UNC System and the State.

- When traveling by vehicle to remote sites, no more than two people should occupy a standard car at a time, and each should always be wearing a University-provided mask. If possible, windows should be open to allow for a constant supply of fresh air.

- **Note Concerning Travel and Parking:** Travel for UNC business is currently restricted to North Carolina and is 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. Information on changes to University parking policies and public transit can be found at the [University Transportation & Parking website](#).
FOR MORE INFORMATION FROM THE VICE CHANCELLOR OF RESEARCH AT UNC:

For overall UNC research information, visit: **DIRECTION AND GUIDANCE FOR ALL ON-CAMPUS RESEARCH AT UNC**

For UNC research lab specific information, visit: **LABORATORY-BASED RESEARCH** for more information

For more information and updates regarding parking on campus, please visit: **University Transportation & Parking website**

The office of the Vice Chancellor of Research will hold periodic Q&A sessions, as needed. More information and scheduling can be found at: **UNC Research COVID-19 website**.

Individuals with questions may email the office at **vcr@unc.edu**.

For additional questions regarding COVID-19, visit the **UNC Coronavirus website** and the **UNC Health Coronavirus website**.