UNCW UNIVERSITY of NORTH CAROLINA WILMINGTON

Research Integrity Office

Institutional Review Board

Questions? Email: IRB@uncw.edu

Directions and Guidance for Restarting Human Subjects Research Paused due to COVID-19

Principal investigators (PIs) who conduct human subjects research must actively work to keep research staff and human subjects safe. It is imperative that research protocols are designed or adapted to minimize risk to human subjects and staff.

As you are aware, conditions relating to COVID-19 are continually changing. Therefore, the ability of UNCW researchers to conduct in-person human subject research (HSR) is also likely to change in response to the changing circumstances. The IRB asks for your understanding and flexibility as we grapple with unprecedented considerations.

Based on current conditions, the IRB believes the following standards are warranted:

1. HSR studies that *do not include in-person participant contact* may continue/resume.
2. HSR studies that include participant interactions *that can be completed virtually or remotely* may continue/resume. Principal investigators (PIs) must ensure that the IRB has approved the virtual/remote activities including any necessary changes to consent forms, and online platform to be used, if applicable. If the new procedures have not yet been approved, PIs must submit a modification form in the IRBIS system to obtain approval prior to initiating new procedures.
3. The UNCW IRB strongly discourages PIs from resuming HSR studies that involve in-person contact with subjects for as long as the state of North Carolina pandemic phase warrants, conditions in New Hanover County indicate a rise in COVID-19 cases, and/or other local or campus conditions indicate in-person contact may increase risk to subjects. PIs who determine they must resume these studies must strictly follow the requirements outlined below, as well as UNCW "Best for the Nest" guidance, and ensure members of the research team comply with all safety protocols.
4. HSR studies that involve *participants of 10 or fewer individuals in a group*, such as a focus group, may resume, provided seating can be arranged to allow 6 feet between group members, one or more hand sanitizer stations are provided, and all focus group participants and research personnel wear face coverings/masks throughout the session. PIs must determine if risks of participation are adequately described on existing consent forms. If not, PIs must obtain approval from the IRB to modify the existing consent form to include possible risks related to COVID-19 and how they will be minimized. Alternatively, the IRB has created a COVID-19 Consent Addendum that PIs may use to describe possible risks of participation and safety precautions that will be taken.
5. PIs may consider if HSR studies can be conducted outdoors rather than in lab settings to avoid enclosed spaces and allow more room for social distancing, which would still be required.
6. HSR studies that required a letter of support from an off-campus facility may only resume if PIs can obtain and submit to the IRB an updated letter of support from the off-campus facility indicating permission for UNCW researchers to be present on the off-campus site. The updated

letter of support must include a statement from the facility that they are implementing safety protocols that abide by applicable CDC recommendations and NC Executive Orders. If a PI will send students to an off-campus facility to conduct research not related to an applied learning course, the students must sign and submit to the IRB a COVID-19 Off-Campus Student Research Waiver. This form is currently under development and will be added to this guidance as soon as it is finalized. Students who conduct off-campus research related to an applied-learning course must follow Applied Learning waiver requirements.

7. HSR studies that require in-person contact with a human subject in an indoor UNCW location may resume *provided the following procedures and any other procedures included in UNCW's Best for the Nest guidance can be followed*:
   a. PIs have evaluated risks and benefits for the participants and can justify to the IRB that resuming the research activities does not increase risk to subjects based on stringent precautions that will be described and followed.
   b. In addition to any required human subject protection training courses, PIs and all members of research team complete two online training courses available through the university's VIVID Learning program (see EH&S's training website for instructions on where to access VIVID Learning courses.) According for Best for the Nest guidance (see page 7), the "Pandemics: Slowing the Spread" and "Cold, Flu, and Transmissible Illness Prevention" courses must be completed.
   c. PIs have determined that research activities can be carried out while complying with social distancing requirements in designated lab or other research space.
   d. All members of the research team conduct a brief self-assessment at the beginning of each shift and agree to discontinue their in-person HSR activity if they begin to show possible COVID-19 symptoms or learn that they have had possible exposure to COVID-19.
   e. Subjects are either instructed in advance to bring a cloth face covering/disposable mask with them or they are provided with a disposable mask upon arrival and are instructed to wear the face covering/mask throughout the session when working with others in shared spaces. Individuals are not expected to wear a face covering/mask when working alone in a room or office. The PI/researcher in charge will end the session and excuse subjects who refuse to wear a face covering/mask.
   f. Subjects are informed in advance that they will not be enrolled in the study at this time if they exhibit COVID-like symptoms and will be informed what symptoms will result in a postponement of participation.
   g. *Prior to a subject's arrival for participation*, research personnel must perform a brief wellness screening for each subject, either by phone or outside the building, consisting of a series of health-related questions (see page 4 below) and decline participation to subjects who display or report possible COVID-19 symptoms or indicate possible exposure to COVID-19. *This procedure must be followed each time a subject appears for a study session.*
      i. If this screening occurs ***the day before*** a subject is scheduled to participate, research personnel will confirm with the subject immediately upon his/her arrival that his/her health status has not changed since responding to the screening questions.
      ii. For health screenings/health status confirmations conducted in-person, research personnel should ensure that they are observing social-distancing (at least 6 feet away), wearing a face covering/mask, and keeping the discussion brief (less than 15 minutes) to best minimize the potential for exposure in the event a subject indicates a possible health concern/change in health status.
      iii. If research personnel postpone a subject's participation due to COVID-19 related concerns, research personnel must disinfect surfaces that the subject touched while present, if applicable.

iv. If research personnel postpone a subject's participation due to COVID-19 related concerns, research personnel will provide the subject with contact information for one of the following and suggest that they call for additional information:
    - If a student: Abrons Student Health Center at 910-962-3280
    - If faculty, staff or community member: New Hanover County COVID-19 Call Center (910-798-6800).

h. Research personnel and subjects must wash their hands for at least 20 seconds with soap and water prior to beginning study activities, before and after any break, and when the study activities are completed. If sinks are not present in meeting space, research personnel and subjects will use hand sanitizer (at least 60% alcohol).

i. Research personnel and subjects wear face masks throughout the study session when working together in shared spaces. Individuals are not expected to wear a face covering when working alone in a room or office.

j. If human subjects will be instructed to use certain equipment during research activities, such as completing a computer task, research personnel must thoroughly clean all surfaces the participant will touch with an appropriate disinfectant wipe immediately before and immediately after the subject's participation, preferably in the presence of the subject so that s/he knows this has occurred.

k. Research personnel wear appropriate personal protective equipment (PPE) in relation to study activities, and PPE is available for use by subjects if subjects request it. PPE includes masks/face shields, gloves and/or gowns. However, full PPE is not required unless study activities warrant that level of protection.

8. In addition to cleaning specific equipment to be used by subjects, PIs must:
    a. Develop and ensure that a regular schedule for frequently cleaning and wiping touched surfaces and objects (e.g., door and cabinet handles, faucets, light switches, keyboards, and other frequently touched objects) is performed with an approved disinfectant or disinfectant wipes.
    b. Disinfect any surface that may be thought to be contaminated.
    c. Use an approved disinfectant such as a 10% bleach or 70% alcohol solution. Please contact the UNCW Environmental Health and Safety or Housekeeping offices with any questions about appropriate cleaning supplies.
9. PIs have a plan in place to track compliance with procedures outlined in #7 and #8 above (checklists, logs, etc.).
10. As part of the ongoing consent process, PIs must ensure that participants understand the potential harms of participating in research. This is particularly important when conducting in-person HSR during a pandemic. PIs planning to conduct in-person activities at this time must either revise consent forms as needed to inform participants of possible risks of exposure to COVID-19 or incorporate the below Consent Addendum describing COVID-related risks and the safety precautions that will be taken to minimize risks. As always, each subject must be given the chance to discuss the expected risks and benefits to make an informed decision regarding participation. Remote consent is encouraged if it allows subjects the opportunity to have questions answered and if approval to use this process has been granted by the IRB. Any changes to the consent form, including the use of the COVID-19 Consent Addendum, must be approved in advance by the IRB through the submission of a modification form.

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COVID-19 Screening Form for Human Subjects Research

Subject Name or ID #:_____

Date of participation: _____

1. As far as you are aware, have you been exposed to anyone with a confirmed COVID-19 diagnosis within 14 days?

   Subject response:

2. Have you tested positive for COVID-19 in the past 14 days?

   Subject response:

3. Have you experienced any of the following:
   - Temperature above 100 degrees
   - Cough and/or shortness of breath (or difficulty breathing)
   - Chills, fatigue, muscle or body aches, headache, new loss of taste or smell, sore throat, congestion or runny nose, nausea or vomiting, diarrhea, or recent history of fever

   Subject response:

4. (*Include only if screening occurs the day before the subject is scheduled to participate.*) Please confirm that you will notify us at (*provide phone number*) if your health status changes before your scheduled participation time. We will also ask you upon your arrival if you have had any changes to your health status.

   Subject confirmed (yes or no):

If answered "YES" to question 1, 2 or 3, do not allow the individual to participate in an in-person human subject research activity at this time. Explain to the person that s/he does not meet the inclusion criteria for the study due to a possible COVID-19 concern, and out of an abundance of caution s/he is not being enrolled at this time. **As appropriate, provide the subject with contact information for one of the following and suggest that they call for additional information:**

- **If a student: Abrons Student Health Center at 910-962-3280**
- **If faculty, staff or community member: New Hanover County COVID-19 Call Center (910-798-6800)**

Research staff member administering screening: _____

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COVID-19
Research Personnel Self-Assessment

Instructions to research team member: Complete this form prior to arriving for your shift.

Research Team Member Name: _____

Date and time of shift: _____

	Circle One
1. As far as you are aware, have you been exposed to anyone with a confirmed COVID-19 diagnosis within 14 days?	**Yes No**
2. Have you tested positive for COVID-19 in the past 14 days?	**Yes No**
3. Have you experienced any of the following: • Temperature above 100 degrees • Cough and/or shortness of breath (or difficulty breathing) • Chills, fatigue, muscle or body aches, headache, new loss of taste or smell, sore throat, congestion or runny nose, nausea or vomiting, diarrhea, or recent history of fever	**Yes No**

If you answered "YES" to any question, please notify the principal investigator or faculty advisor of this study that you are unable to work your shift due to COVID-19-like symptoms or possible exposures. Additionally, please consider contacting either the New Hanover County COVID-19 Call Center at 910-798-6800 (if you are faculty or staff) or the Abrons Student Health Center at 910-962-3280 (if you are a student).

If you responded "NO" to all questions, please read the following statement and sign below:

I understand that by signing this form, I attest that as a human subject researcher, it is my responsibility to protect human subjects from harm in accordance with approved procedures and precautions. If I begin to develop COVID-19-like symptoms (as listed above), or learn that I have been exposed to someone who has been diagnosed with COVID-19, I will immediately remove myself from the research setting, cancel appointments with human subjects as necessary, and notify the PI and/or faculty advisor of the study of my change in condition.

Signed: _____ **Date:** _____

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Informed Consent Addendum
Risks and Safety Precautions Due to COVID-19

UNCW Principal investigators (PIs) who conduct human subjects research must actively work to keep research staff and human subjects safe. As a possible participant in a UNCW research study, we are providing you with this additional information in an effort to keep you fully informed about risks associated with participating in a research study and safety precautions that will be taken to minimize risks.

We want you to be aware that although we will make every effort to maintain your health and well-being throughout your participation, we cannot guarantee that you will not have exposure to the COVID-19 virus during your participation in this research study.

Indicated below by the checked items is our plan to maintain the safest conditions possible for research participants and research personnel. ***Please understand that if you are a member of a group that has a higher risk of severe impacts from COVID-19, you should consider CDC guidelines when deciding if you want to participate in an in-person research activity at this time.***

Study Identification:

Study Name: _____

IRB Approval #: _____

☐ The research activities will take place outdoors to avoid enclosed spaces and allow more room for social distancing. The new meeting location is:

_____

☐ We have obtained approval from the off-campus meeting location giving us permission to use the facility provided we follow the precautions noted below. This facility has confirmed with us in writing that they are following CDC guidelines for safety.

☐ Research staff have completed an online COVID-19 Safety training course.

☐ Research staff will comply with social distancing requirements in study locations.

- ☐ Before arriving for each shift, research staff members are required to conduct a brief wellness self-assessment consisting of answering several health-related questions and signing a statement saying they will follow all approved procedures to protect your well-being and cancel research appointments if they begin to feel unwell or learn that they might have been exposed to COVID-19.

- ☐ We will require you to bring a cloth face covering or disposable face mask with you. If you are unable to bring a face covering/mask, please let us know and we will have one available for you. We will require you to wear a face mask throughout the session when in the presence of others.

- ☐ Before you arrive, we will perform a brief wellness screening with you, consisting of asking you several health-related questions. Please understand that in order to protect everyone's safety, we will not permit you or any subject to participate in this research if you have possible COVID-19 symptoms (temperature above 100 degrees, cough and/or shortness of breath (or difficulty breathing), chills, fatigue, muscle or body aches, headache, new loss of taste or smell, sore throat, congestion or runny nose, nausea or vomiting, diarrhea, or recent history of fever), if you indicate possible exposure to COVID-19 in the past 14 days, or have tested positive for COVID-19 in the past 14 days. We may have to ask you to postpone your participation, and may suggest you contact either the UNCW Student Health Center if you are a UNCW student or the New Hanover County COVID-19 Call Center at 910-798-6800 if you are not a UNCW student.

- ☐ Research staff and participants will either wash their hands for 20 seconds using soap and water or use hand sanitizer prior to beginning study activities.

- ☐ Research staff will be required to wear face masks and/or other personal protective equipment (PPE) as appropriate (like gloves, gowns, etc.), and PPE will be available for your use if appropriate or upon your request.

- ☐ If we will ask you to touch equipment in our lab, such as a computer or other instrument, we will thoroughly clean all surfaces you will touch with an appropriate disinfectant wipe immediately before and immediately after your participation.

- ☐ We have developed and will ensure that a regular schedule for frequently cleaning and wiping touched surfaces and objects (e.g., door and cabinet handles, faucets, light switches, keyboards, and other frequently touched objects) is performed with an approved disinfectant or disinfectant wipes.

- ☐ We have a plan in place (such as checklists, logs, etc.) to track compliance with the procedures above that are checked.

☐ We will contact you if, following your participation, we become aware that you may have come in contact with someone who tests positive for COVID-19.

If you have any questions about the information provided above, please contact the principal investigator of this study:

Principal Investigator Name: _____

Phone Number: _____

Email: _____

If you would like to speak to someone who is not involved with this study, but who can explain your rights as a research subject, you may contact the UNCW Institutional Review Board at irb@uncw.edu or 910-962-7774.

For UNCW campus COVID questions, please email coronavirus@uncw.edu.

If you would like to obtain information regarding COVID-19 in New Hanover County, please call the New Hanover County COVID-19 Call Center at 910-798-6800.

By signing this form, you indicate the you have read and understand the information provided above and have had an opportunity to ask questions. You also indicate your understanding that participating in an in-person research study at this time may expose you to the COVID-19 virus, your participation is voluntary, and you may stop participating at any time.

Participant Signature: _____

Phone Number: _____

Email: _____