



COLLEGE OF ARTS AND SCIENCES
Exercise and Sport Science

Policies & Procedures for Resuming Human Subjects Research

June 17, 2020

Research Activity on the UNC Campus

General Information

- Phase I of the research ramp-up began on June 1
- Research that can be conducted remotely should continue to be conducted remotely
- Departments will develop individual plans for approval by the College and OVCR

Allowable research activities

- Research is no longer restricted to “critical research activities” and no longer requires OVCR approval
- Human subjects research must conform to the OVCR, College, and Department guidelines outlined below
- Resuming IRB-approved research and initiating new research protocols requires Departmental approval



Research Activity on the UNC Campus

- Guidance from the University about resuming research can be found here and in the [Carolina Roadmap](#)
- Additional guidance from the Office for the Vice Chancellor for Research can be found [here](#)
- This document outlines specific policies and procedures for resuming research activities in the facilities operated by the Department of Exercise & Sport Science
- On overview of the EXSS guidelines and other relevant information relative to COVID-19 can be found on the [EXSS COVID-19 Resources website](#)



General Information about COVID-19

- COVID-19 is a respiratory diseases caused by the SARS-CoV-2 virus
- The virus is spread though physical contact with people or objects when respiratory droplets are expelled from an infected person when he/she coughs, sneezes, or even talks
- **Not all infected people display symptoms**, but common signs and symptoms include
 - Coughing
 - Shortness of breath or difficulty breathing
 - Fever
 - Repeated shaking with chills
 - Muscle pain
 - Sore throat
 - New gastrointestinal symptoms
 - Sudden loss of taste or smell

EXSS Research Procedures

- Researcher training and workplace expectations
- Laboratory safety plans
- Laboratory cleaning protocol
- PPE procurement and use guidelines
- Risk/benefit review process
- IRB considerations

EXSS Research Documents

- Several documents related to resuming research operations are referenced throughout this document and can be accessed on [EXSS COVID-19 Resources website](#)
 - EXSS Documents for Research
 - Departmental approval process and form
 - Project-Specific Safety Plan form
 - Lab Safety Plans
 - EXSS Employee Wellness Form
 - EXSS Research Participant Wellness Form
 - Required COVID-19 safety training
 - IRB documents
 - Required COVID-19 Information Sheet
 - Informed consent/Modification procedures

Researcher Training & Workplace Expectations

- Required training
 - All research personnel must complete the online [UNC Environment, Health and Safety COVID-19 safety training](#) prior to resuming research activities
 - The training requires entry of an email address for a person to whom verification of course completion will be sent
 - Enter troyb@email.unc.edu in this text box
 - Upon completion of the quiz verification emails will be sent to this individual and to you
 - Research personnel should forward the verification email they receive to the study PI or their research mentor

Researcher Training & Workplace Expectations

- Individuals who can work from home should continue to do so
- Meetings involving multiple personnel should continue to take place remotely
- Individuals who return to campus to conduct research **must confirm each day** that they do not have any COVID-19 signs or symptoms using the EXSS Employee Daily Wellness Checklist
- Individuals with COVID-19 signs and symptoms should contact their health care provider for guidance
- Individuals who test positive for COVID-19 must not return to campus until they are approved to do so by the Employee Occupational Health Services or Campus Health Services



Researcher Training & Workplace Expectations

- Daily Employee Wellness Checklist
 - To be completed each day prior to entering research facilities
 - If you are experiencing any COVID-19 symptoms do not attend class, work, or any other campus activities, and contact your medical provider as soon as possible
 - If you test positive for COVID-19 you must not return to campus facilities until cleared to do so by your health care provider
 - If you experience COVID-19 symptoms or test positive for COVID-19 **you must inform the PI and Lab Director**

EXSS Daily Employee Wellness Checklist

- Do you feel like you may have a **temperature greater than 100° F?** (If yes, take temperature)
Yes ____ Temperature ____ No ____
- Do you have **new muscle aches** not related to another medical condition or another specific activity (e.g. due to physical exercise)?
Yes ____ No ____
- Do you have a **sore throat** not related to another medical condition (e.g. allergies)?
Yes ____ No ____
- Do you have a **new or worsening cough** that is not related to another medical condition?
Yes ____ No ____
- Do you have **shortness of breath** that is not related to another medical condition?
Yes ____ No ____
- Do you have **recent (<5 days) loss of smell or taste?**
Yes ____ No ____
- Do you have new onset of **vomiting or diarrhea** not related to another medical condition?
Yes ____ No ____
- Have you had recent close contact with someone who has tested positive for COVID-19?
Yes ____ No ____

If you answered yes to any of the questions above, please do not attend class, work or other campus activities and contact your medical provider.



COLLEGE OF ARTS AND SCIENCES

Exercise and Sport Science

Researcher Training & Workplace Expectations

- Research spaces must be used exclusively for the conduct of research (i.e. not as office or meeting space)
- Occupancy of research spaces is restricted to **1 person per 200 ft²** of space
- **Physical distancing of at least 6 ft should be maintained at all times**
 - Closer interaction with research subjects (e.g. donning sensors) is permissible, but should be limited and should involve additional PPE (e.g. gloves) where appropriate
 - Additional PPE (e.g. face shields) may be necessary in instances when it is not feasible for the participant to wear a PPE mask (e.g. during a maximal exercise test)
- **PPE masks should be worn by all individuals at all times** including researchers, research participants, and visitors
- Doors to research facilities should **remain closed at all times**
 - Only research personnel should open doors for entry/exit to reduce COVID-19 transmission risk at “high touch points”

Laboratory Safety Plans

- Each EXSS laboratory will develop a Safety Plan
 - Employee wellness screenings, subject wellness screenings, and laboratory cleaning plans will be consistent across all research spaces
 - Some spaces may require additional screening and cleaning procedures for enrolling high-risk research participants or unique testing scenarios
- Each lab's safety plan can be accessed via the [EXSS COVID-19 Resources website](#)
 - Applied Physiology Laboratory
 - Exercise Oncology Laboratory
 - Gfeller Center
 - Human Performance Center
 - MOTION Science Institute (Gait Biomechanics, Motion Analysis, Neuromuscular, and STAR Heel Laboratories)



Laboratory Safety Plans

- Participant screening procedures
 - All subjects must complete the EXSS Research Participant Wellness Checklist two times
 - 24 hr telephone wellness screening
 - Arrival screening

EXSS Research Participant Wellness Checklist

	YES	NO
Do you feel like you may have a temperature greater than 100° F? (If yes, take temperature). Temperature _____		
Do you have new muscle aches not related to another medical condition or activity (e.g. exercise)?		
Do you have a 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 related to another medical condition?		
Do you have recent (<5 days) loss of smell or taste?		
Do you have new onset of vomiting or diarrhea not related to another medical condition?		
Have you had recent close contact with someone who has tested positive for COVID-19?		
Have you tested positive for COVID-19?		
Have you been quarantined due to COVID-19 symptoms?		

• If you answered **Yes** to either of the previous two questions:

- Date of positive COVID-19 test: _____
- Date when asymptomatic: _____
- Have you been cleared by a physician to resume physical activity/exercise? YES ____ NO ____

Participant:

Name: _____

Signature: _____ Date: _____

EXSS Research Personnel:

Name: _____

Signature: _____ Date: _____



Laboratory Safety Plans

- Participant screening procedures
 - Telephone wellness screenings ***must be conducted within 24 hrs prior to arrival***
 - Email or electronic survey permissible but telephone preferred
 - Document in research files
 - Only subjects who answer “No” to all questions can arrive for testing the following day
 - Subjects who answer “Yes” to any questions should be encouraged to contact their health care provider
 - Potential subjects who have previously tested positive for COVID-19 or have quarantined due to COVID-19 symptoms must be asymptomatic for at least 14 consecutive days prior to enrolling in an EXSS study. These individuals must additionally be screened and cleared by a physician prior to engaging in studies involving vigorous physical activity



EXSS Research Participant Wellness Checklist

	YES	NO
Do you feel like you may have a temperature greater than 100° F? (If yes, take temperature). Temperature _____		
Do you have new muscle aches not related to another medical condition or activity (e.g. exercise)?		
Do you have a 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 related to another medical condition?		
Do you have recent (<5 days) loss of smell or taste?		
Do you have new onset of vomiting or diarrhea not related to another medical condition?		
Have you had recent close contact with someone who has tested positive for COVID-19?		
Have you tested positive for COVID-19?		
Have you been quarantined due to COVID-19 symptoms?		

- If you answered **Yes** to either of the previous two questions:

- Date of positive COVID-19 test: _____
- Date when asymptomatic: _____
- Have you been cleared by a physician to resume physical activity/exercise? YES _____ NO _____

Participant:

Name: _____

Signature: _____ Date: _____

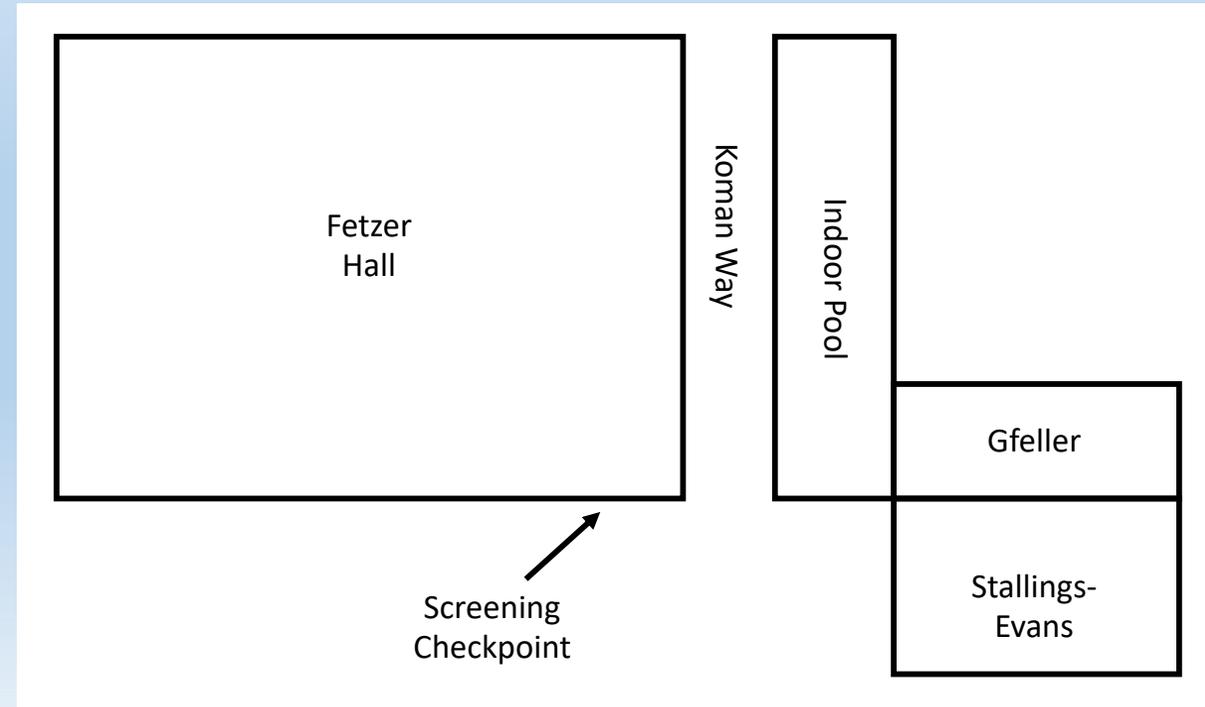
EXSS Research Personnel:

Name: _____

Signature: _____ Date: _____

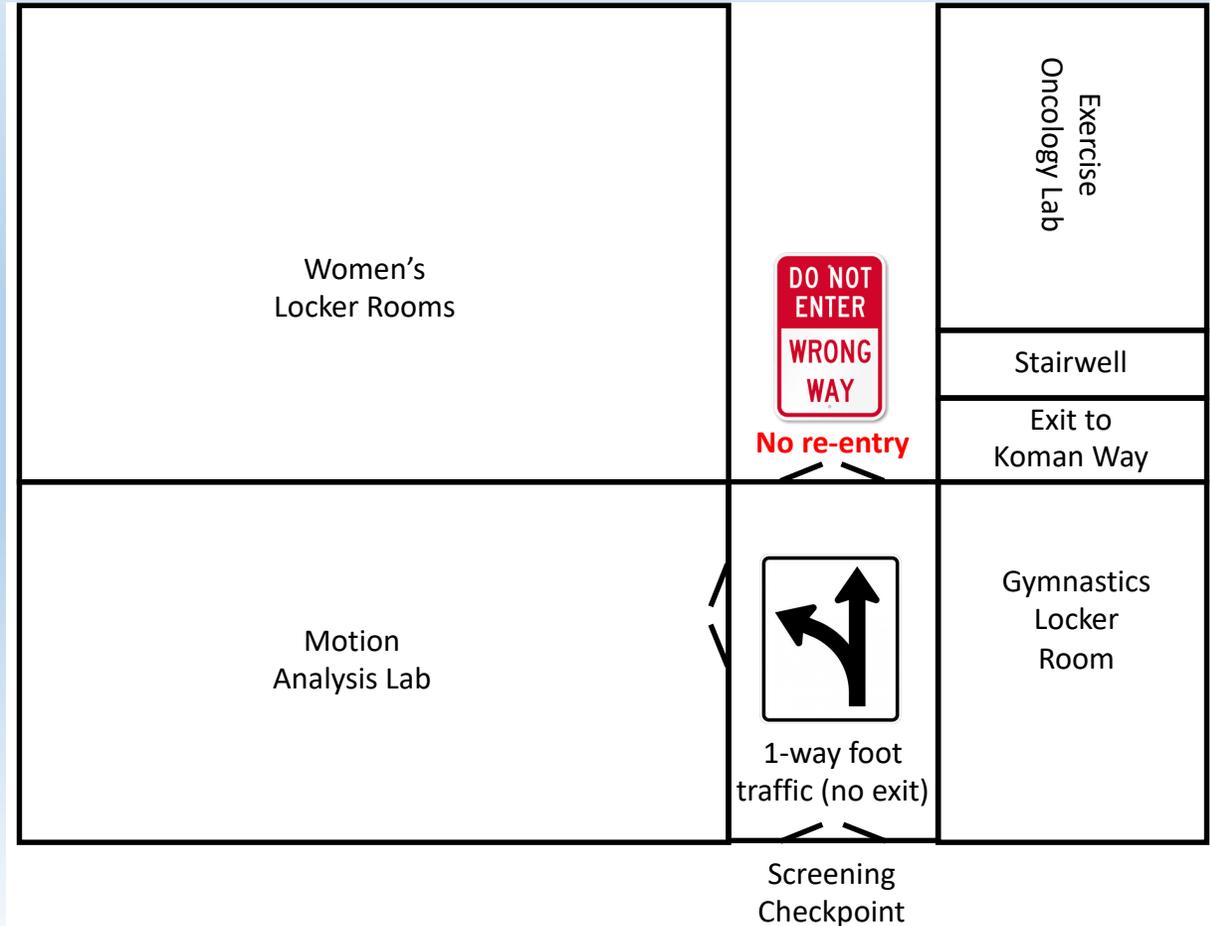
Laboratory Safety Plans

- Participant screening procedures
 - Arrival screenings (day of testing)
 - **All research participants must be screened at the southeast entrance to the basement floor of Fetzer Hall prior to entering EXSS labs**
 - Research personnel should make arrangements for meeting participants at the checkpoint upon arrival
 - A designated member of the research team for the specified study will be responsible for conducting the participant arrival screening



Laboratory Safety Plans

- Participant screening procedures
 - Arrival screenings (day of testing)
 - **Participants who pass the arrival screening**
 - Document screening in research files
 - Green sticker placed on chest
 - Escorted to the laboratory for testing
 - Escorted back to a building exit (**not the screening checkpoint**) following testing



Laboratory Safety Plans

- Participant screening procedures
 - Arrival screenings
 - **Participants who fail the arrival screening**
 - Instructed to exit the building and contact health care provider
 - PI, Lab Director, and Department Chair should be notified of potential COVID-19 exposure
 - Follow up with UNC
 - **Screening procedures must temporarily be halted so that the area can be disinfected**
- Important contact information
 - UNC COVID-19 Helpline (888-850-2684)
 - [UNC Campus Health](#) (919-966-2281)
 - [UNC Employee Occupational Health Clinic](#) (919-966-9119)
 - [UNC Environment, Health, & Safety](#) (919-962-5507)



Laboratory Safety Plans

- High-risk populations
 - Per the US Center for Disease Control and Prevention (CDC) individuals at high risk for severe illness from COVID-19 include
 - Individuals 65 years of age and older
 - Individuals who live in a nursing home or long-term care facility
 - Individuals of all ages with underlying medical conditions, particularly if not well-controlled
 - Chronic lung disease or moderate to severe asthma
 - Heart conditions
 - Individuals who are immunocompromised
 - Many conditions can cause a person to be immunocompromised, including cancer treatment, smoking, bone marrow or organ transplantation, immune deficiencies, poorly controlled HIV or AIDS, and prolonged use of corticosteroids and other immune weakening medications
 - Severe obesity (body mass index [BMI] of 40 or higher)
 - Diabetes
 - Chronic kidney disease undergoing dialysis
 - Liver disease

Laboratory Safety Plans

- High-risk populations
 - Many EXSS research studies may encounter individuals at high-risk for severe illness from COVID-19
 - Cancer patients, obese individuals, osteoarthritis patients, retired athletes, etc.
 - Additional precautions may be necessary to protect participants in these groups and should be indicated in Lab Safety Plans and the Risk/Benefit review proposal for each study
 - The additional risk of COVID-19 exposure must be weighed relative to the potential benefits of the study to the participants and/or society at large

Laboratory Safety Plans

- Other visitors
 - Individuals occupying EXSS research facilities should be limited to research personnel and research participants except under unique circumstances
 - Other individuals (e.g. parents of minor participants and legally authorized representatives) can enter the research facility but must:
 - Observe social distancing guidelines
 - Adhere to occupancy criteria (1 person per 200 ft²)
 - Utilize PPE masks

Laboratory Cleaning Protocol

- If the research facility has not been occupied in the last 7 days → **schedule routine cleaning** (i.e. normal cleaning practices for the university)
- If area has not been occupied in the last 7 days → **schedule routine cleaning** for surfaces **not** frequently touched
- For frequently touched surfaces, the cleaning procedures outlined on the following page should be utilized

Laboratory Cleaning Protocol

Frequently touched surfaces or objects

Hard and non-porous materials (e.g. glass, metal, or plastic)

- Visibly dirty surfaces should be cleaned with soap and water prior to disinfection
- Use an EPA-approved disinfectant against COVID-19
- Wear gloves and wash your hands after removing the gloves

Soft porous materials (e.g. carpet, rugs)

- Thoroughly clean or launder materials
- Wash laundered items using the warmest appropriate water setting
- Consider removing soft porous (e.g. rugs) materials in high traffic areas
- Clean and disinfect hampers/carts for transporting laundry
- Wear gloves and wash your hands after removing the gloves

Electronics

- Follow manufacture instructions for all cleaning and disinfection products
- If no manufacturer guidance is available, consider the use of alcohol-based wipes or sprays containing at least 70% alcohol to disinfect touch screens
- Dry surfaces thoroughly to avoid pooling of liquids
- Wear gloves and wash your hands after removing the gloves



Laboratory Cleaning Protocol

- EPA-recommended disinfectants can be found [here](#)
 - Commonly-available products from Clorox can be found [here](#)
- Each laboratory should use sign-off logs to verify compliance with the established cleaning protocol

PPE Procurement

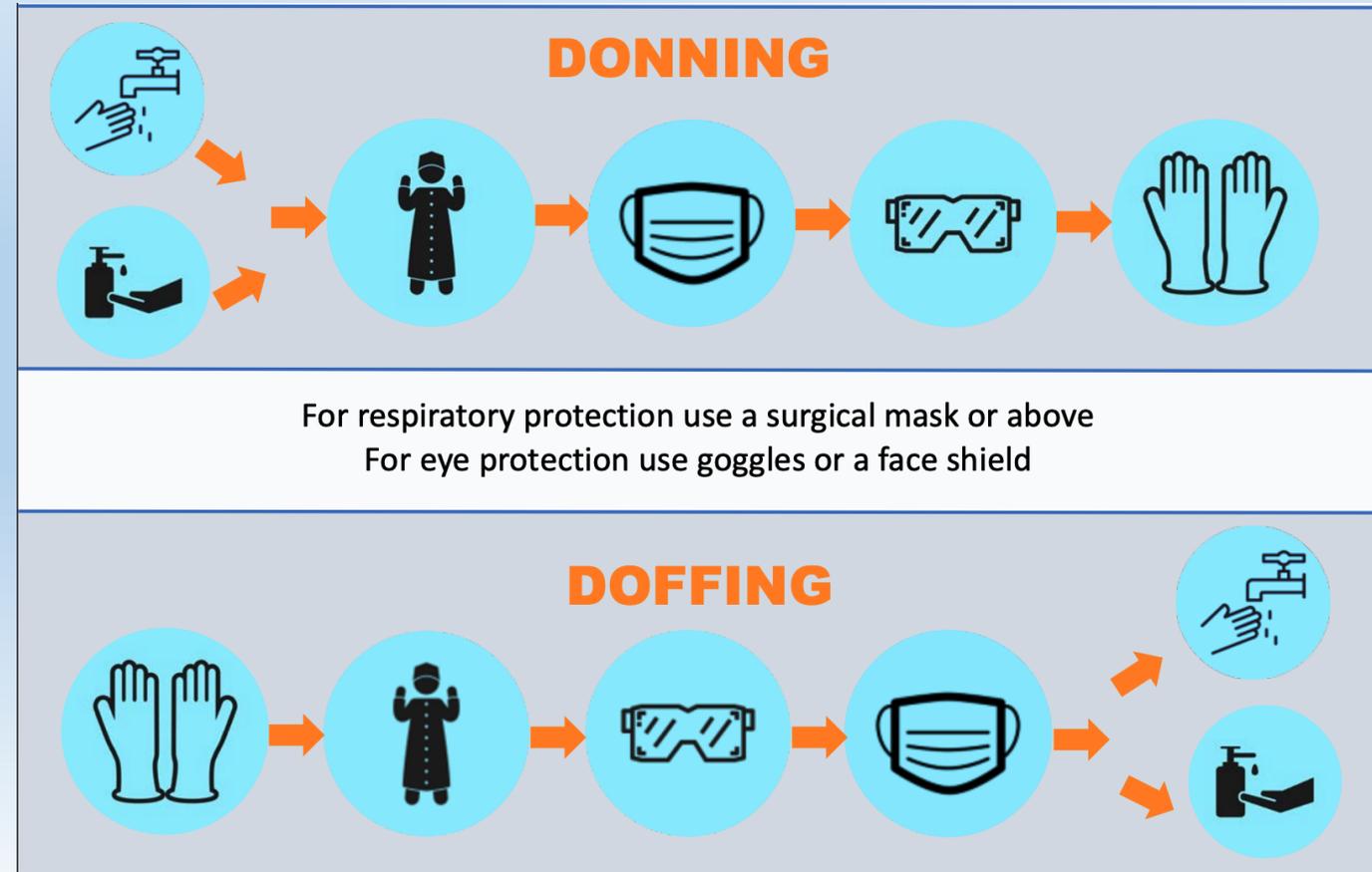
- PPE will be acquired weekly from the College for research labs
 - “PPE Kits” will be acquired for each lab every Monday
 - 50 masks, 500mL bottle of 70% ethanol, paper napkins in bundles, TOPO hand sanitizer in 500 ml squirt bottles, Clorox wipes
 - Darrell Kidd should be notified 1 week in advance if a kit is not needed the subsequent week
- Gloves and extra cleaning supplies need to be ordered through the Department every 2 weeks when necessary
 - Gloves and cleaning supply orders should be emailed to Darrell Kidd on the 1st and 3rd Monday of each week before noon
 - Orders will be delivered to the laboratories

PPE Use Guidelines

- Only University-issued PPE masks should be utilized in laboratories (i.e. not personal/cloth masks)
- PPE masks are intended for **2 days of use (i.e. two 8-hour shifts)**
 - Masks can be reused and should be stored in a paper bag labeled with the individual's name
 - Masks should not leave the research facility (i.e. only intended for research-related use) and should be stored appropriately for use during the next shift
 - The mask should be stored in the paper bag any time it is removed (e.g. to allow eating, drinking, or use of the restroom)
 - To store the mask, it should be folded so that the outer surface (subject-facing, potentially contaminated side) is held inward and against itself to reduce contact with the bag during storage
 - If a mask becomes damaged or visibly soiled it should be replaced
 - Disposable masks cannot be laundered

PPE Use Guidelines

- Donning PPE masks for reuse
 - Wash your hands before donning any PPE
 - Always **apply your mask first** and gloves (if applicable) last
- Doffing PPE masks for reuse
 - Always **remove gloves first** (if applicable) and your mask last
 - Always wash your hands after removing and storing PPE



Risk/Benefit Review Process

- All human subjects research must go through a Departmental approval process to ensure the additional risk of COVID-19 exposure is weighed against the potential benefits of the study for participants and/or society at large
 - Submission requirements, forms, and the details of the process can be found on the [EXSS COVID-19 Resources website](#)
- Steps for submitting proposals for Departmental review
 1. Review EXSS Resuming Research Policies & Procedures
 2. Review the Lab Safety Protocols for the research space(s) to be used for the proposed study
 3. Complete the required UNC Environment, Health, & Safety COVID-19 online training
 4. Develop a Project-Specific Safety Plan
 5. PIs coordinate with Lab Directors to ensure study feasibility and review the Project-Specific Safety Plan
 6. Submit the online review form



IRB Considerations

- Previously approved studies **do not** require additional IRB review unless modifications are necessary
 - Only departmental approval is necessary
- Investigators must provide subjects with the IRB-COVID Information Sheet
 - This document outlines the risk of COVID-19 and the risk mitigation strategy for the respective research space(s)
 - This form is designed to provide information only – **it does not need to be signed**
 - The conversation with participant and the outcome of the discussion should be documented in the participant's research record
 - The participant should receive a copy

IRB Considerations

- IRB-COVID Information Sheet
 - Form must be updated with study information but does not require approval as long as the only edits are to the “X’s”
 - Subjects must be informed of any study procedures that could violate physical distancing guidelines
 - Spanish version also available



University of North Carolina at Chapel Hill
Information about participating in a Research Study during COVID-19.

Version Date: XXXXXX
IRB Study # XX-XXXX
Title of Study: XXXXXXXXXXXX
Principal Investigator: XXXXXXXXXXXX
Study Contact Telephone Number: XXXXXX
Study Contact Email: XXXXXX

The “you” referenced in this information sheet either refers to the participant, “your child”, or the individual you are providing consent on behalf of as a legal authorized representative, as applicable.

The following information should be read as an addition to the original Consent process. Unless specifically stated otherwise in the following paragraphs, all information contained in that original Consent Form is still true and remains in effect. Your participation continues to be voluntary. You may choose not to participate or may withdraw your consent to participate at any time, and for any reason, without jeopardizing your future care at this institution or your relationship with your study doctor.

New or additional information

COVID-19 is a novel (previously unidentified) coronavirus and has been declared a pandemic due to its global spread. The virus causing coronavirus disease 2019 (COVID-19), is not the same as the coronaviruses that commonly circulate among humans and usually cause mild illness, like the common cold. Many countries, states, and local governments have implemented restrictions (e.g., physical distancing requirements, closure of public places) to attempt to limit the spread of the virus. If your community does not permit travel or otherwise limits interaction, please tell the study team. UNC’s permission for certain studies to continue is not intended to interfere with a person’s ability to follow their community’s requirements.

Physical distancing is the primary strategy used to prevent the spread of the virus that causes COVID-19. Physical distancing calls for people to increase the space between one another and to avoid gatherings and crowds. The Centers for Disease Control and Prevention (CDC) says people should maintain a distance of at least six feet from others when possible.

If you chose to continue your participation in research at UNC, UNC research personnel will do their best to follow the below recommendations described in this information sheet that were developed based on guidance from the CDC and in partnership with study teams, departments, and UNC’s Infectious Disease specialist. Despite everyone’s efforts, there is still the risk that you may already have or may become infected with COVID-19 and may then infect others.

COVID-19 Symptoms

People with COVID-19 have had a wide range of reported symptoms – ranging from mild symptoms to severe illness which may lead to death. Symptoms may appear 2-14 days after exposure to the virus. People with these symptoms may have COVID-19:

- Cough
- Shortness of breath or difficulty breathing
- Fever
- Chills especially repeated shaking chills
- Muscle pain
- Sore throat
- New loss of taste or smell
- Vomiting and diarrhea

This list is from the CDC but may not include all possible symptoms. People experience the virus in many different ways. Please contact your medical provider if you are experiencing symptoms that are concerning to you.

Pandemics can be stressful for everyone. Fear and anxiety about a disease can be overwhelming and cause strong emotions in both adults and children. Please talk with the study team if you are experiencing COVID symptoms, fear or anxiety.

IRB Considerations

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.

Risk Level/Regulations	Full Waiver of HIPAA and Consent	Alt. Or Waiver of Signature (Verbal)	Signature is Required
Minimal Risk-No Intervention/Interaction with subjects *Expedited Categories	Yes	Likely NA	Likely NA
Minimal Risk- Intervention/interaction with subjects *Expedited Categories	Likely NA	Yes	If possible, (for electronic consider Qualtrics, REDCap or other IT approved mechanism)
Greater than minimal risk- Full board	NA	NA	Yes (for electronic signature consider Qualtrics, REDCap or other IT approved mechanism)
Greater than minimal risk-Full Board FDA Regulated	NA	NA	Yes (for electronic signature must be Part 11 Compliance, check with IT Liaison)

IRB Considerations

COVID Submission Table-IRB-UPDATED 5/22/2020

*Please note that this has been permitted by your departments plan and OVCR's guidance in regard to PPE, social distancing requirements when possible. If the OVCR's guidance cannot be followed this should be identified with additional analysis provided of how risks will be mitigated.

Type of Change	Risk Analysis State.	COVID State. in Cover Page	Included in Mod Desc.	Updated Consent Section in App	Updated Through-out App	Attach.	Consent Form
Activities Modified due to and during COVID only (No Consent Changes)	Yes	Yes*	Yes	No	No	As appl. e.g., Letters from Sponsor	No
Activities Modified due to and during COVID only (Consent Form Changes)	Yes	Yes*	Yes	Yes-Outline remote proc. As needed	No	As appl. e.g., Letters from Sponsor	Yes
Activities Modified for COVID and other study changes	Yes	Yes*	Yes, outline all changes	As appl. Outline Remote Proc. As needed	As appl.	As appl.	As Appl.
New COVID Related Study	NA	Yes*	NA	Outline Remote Consent Proc. As needed	NA	All, including any FDA documents, or IND/IDE worksheets	Consider: -FDA App. -Assay -Return Results
Adding COVID Aims to existing study	Yes	Yes*	Clearly outline how this is within current research question	As appl. Outline Remote Proc. As needed	Yes	As appl.	Consider: -FDA App. -Assay -Return Results



Safety Monitoring & Compliance

- Per University guidelines
 - Research facilities and buildings will be monitored periodically to ensure required safety measures are being practiced
 - Anyone found to be out of compliance with these required measures will be counseled on the need for compliance with the required practices outlined in this guidance
 - Further instances of non-compliance may result in the employee being subject to disciplinary measures in accordance with applicable University policies
- Compliance with required practices is a shared community responsibility.
 - Individuals may report non-compliance by calling the Ethics Point Hotline at (866) 294-8688
- The director of each laboratory will be responsible for maintaining cleaning regimens and enforcing the Laboratory Safety Plan

