

CTRC COVID-19 Specific FAQ's and Helpful Information

Table of Contents

- [Employee/Provider Self-Screening Prior to Entering CTRC](#)
- [Hours of Operation](#)
- [Building Badge Readers](#)
- [Mask Policy for Staff & Study Personnel](#)
- [Eye Protection](#)
- [Visitor/Companion Restrictions](#)
- [Participant Reminder to Self-Screen for COVID Symptoms & Appointment Confirmation](#)
- [Participant and Companion Masks](#)
- [Patient Care Room Limits](#)
- [Participant Check-In Process](#)
- [Triage Process, Rooming & Reserving Rooms Prior to Participant Arrival](#)
- [Exam Room Cleaning & Dry Erase Board](#)
- [Participant Checkout Process](#)
- [Appointment Reminder Email](#)
- [Phlebotomy](#)
- [Blood Volume and Times](#)
- [Specimen Processing & Storage Facility \(Room 1035\)](#)
- [Processing Specimens](#)
- [Specimen Storage and Transport](#)
- [Respiratory Samples](#)
- [Symptomatic Participants & Companions](#)
- [Hand Hygiene & Glove Usage](#)
- [Practicing Physical Distancing](#)
- [Coordinator Meal Breaks](#)
- [Conference Room \(Workspace, Meal Breaks and Trainings/Meetings\)](#)
- [Research Participant Snacks & Nourishment Room](#)
- [Clean Utility Room](#)
- [Linen and Paper Products](#)
- [Tours of the CTRC, Monitor & Site Qualification Visits](#)
- [Patient Transportation](#)
- [Internal Route from Memorial Hospital to Burnett-Womack](#)
- [Additional Resources](#)

CTRC COVID-19 Specific FAQ's and Helpful Information

Follow [Universal Pandemic Precautions](#), wash your hands frequently and properly, and do not come to work if you are sick!

If you have questions about your wellness, you are advised to contact a health care provider, [University Employee Occupational Health Clinic](#) or by calling 919-966-9119.

As much as possible, study personnel should recognize symptoms of COVID-19 (listed below) prior to reporting to the workplace and not enter the CTRC without first receiving clearance from [UEOHC](#) if any of the below symptoms are present or you have tested positive for COVID-19 in the last 21 days. If symptoms begin while in the CTRC, immediately leave the work environment, complete the [COVID-19 Wellness Check](#) and await further instructions from UEOHC personnel.

- Cough
- Shortness of breath
- Loss of taste or smell
- Sore throat
- Fever or feeling feverish
- Repeated shaking with chills
- Muscle pain
- Vomiting or diarrhea
- Or have tested positive in the last 21 days for COVID-19

Additionally, every effort should be made to enter the CTRC via the “Authorized Personnel Door” in the middle hallway off the front lobby of Burnett-Womack to reduce the amount of traffic in the waiting room.

Hours of Operation

Normal hours of operation resumed on June 8th, 2020. Any changes in hours of operation will be communicated through the CTRC News Listserv.

- Monday – Thursday: 7:30 am – 5 pm
 - Friday: 7:30 am – 1 pm
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Burnett-Womack and CTRC Badge Readers

Front entry doors into the Burnett-Womack building will be open or “on green” during normal university business hours and badge access will be required outside of these hours. Badge readers located in the CTRC will automatically turn “green” during the hours of 7:20 am to 5 pm Monday – Thursday and from 7:20 am – 1 pm on Friday. Note, access to UNC Medical Center requires hospital access in certain

CTRC COVID-19 Specific FAQ's and Helpful Information

buildings (i.e., leaving Burnett-Womack and entering Old Infirmary, returning to UNC Medical Center from Brinkhous-Bullitt).

Mask Policy for Staff and Study Personnel

As part of the continuing efforts to keep our patients and co-workers safe, a new ear loop mask will be provided each day for all staff and providers working in the CTRC until further notice. Masks will be available on a cart located outside of room 1045 (Conference Room).

Make sure to follow the steps listed below [in this video](#) as well as this video on [simple tips to improving the fit of your mask](#) to ensure you wear your mask correctly. You may wear a personal mask when walking into or out of the CTRC (before arriving to the CTRC or when leaving after your activities are completed). However, once you arrive to the CTRC, you must wear the new mask provided. Highlights of the [policy](#) include:

- Perform hand hygiene (hand sanitizer or wash with soap), and then put on your mask.
- Try not to touch your mask once you have it on; if you do touch or adjust your mask you should immediately perform hand hygiene.
- Masks are to be worn continuously during the shift of work, except when leaving the work areas or taking breaks to eat or drink.
- Masks must be removed/discarded if they become soiled, damaged, hard to breathe through, or if they have been used for 1 work shift.
- Remove your mask by releasing the ear loops or by untying the bottom and then the upper tie and pulling away from your face. Do not remove by grasping the front of the mask.

Please remember that wearing a mask is just one component of our plans to keep everyone safe. We must also perform proper hand hygiene, and take care of ourselves and each other.

Eye Protection

UNC Health's Universal Pandemic Precautions are safe, sustainable practices that protect you from exposure to infectious agents. To maintain alignment with UNC Medical Center policies, individuals are recommended to wear eye protection in addition to a face mask for all participant/companion encounters.

- [Eye protection](#), in addition to a face mask, is recommended for any participant interaction including consenting.
 - Eye protection includes either a full-face shield, reusable frame with eye shield, over glasses safety goggles, or goggles.
 - Eye protection *DOES NOT* include standard prescription or reading glasses (even with side shields), contact lenses, clip-on side shields for glasses, safety glasses with side

CTRC COVID-19 Specific FAQ's and Helpful Information

vents, safety glasses that don't wrap around to the temples or provide complete front and side coverage.

- Eye protection should be disinfected and reused:
 - Wipe eye protection 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.
 - Eye protection is required anytime you are working in the Specimen Processing and Storage Facility (room 1035).
 - Any aerosol generating procedures must be approved by CTRC leadership prior to the visit being scheduled. [Aerosol generating procedures](#) are performed with gown, respirator (N95 or CAPR), eye protection, and gloves.
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Visitor/Companion Restrictions

While UNC Health's [visitor policy](#) does allow for companions to attend certain ambulatory visits, the CTRC will continue to restrict the number of companions allowed in the CTRC outpatient unit for the foreseeable future. However, we continue to encourage individuals who are able to come alone to do so in order to support physical distancing efforts and minimize risk. All companions will be subject to the same participant screening and mask policies as described elsewhere in this document. Highlights of the policy include:

- Up to two parents/guardians per pediatric participant
 - One companion per adult participant
 - No companions under the age of 18 will be allowed to visit for the foreseeable future except for non-ambulatory infants
 - Companions who are over 65, pregnant or immunocompromised are discouraged from visiting
 - Any companions who are allowed entry into the CTRC must pass a health screening. Companions should not visit the CTRC if they have one or more of the following symptoms—fever, cough, or shortness of breath (or other symptoms listed elsewhere)—or have come into contact with a person who tested positive for COVID-19 in the last 14 days.
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Participant Reminder to Self-Screen for COVID Symptoms & Appointment Confirmation

On May 4th, 2022, UNC Medical Center ended the requirement of patients and visitors being screened for COVID symptoms at the entry door and instead they are now being asked to [self-screen for symptoms of COVID-19](#) or in other words, hospital staff are no longer manning the front doors and asking the travel screening questions before a patient or visitor is allowed to enter.

Due to this change, the CTRC no longer requires coordinators to call the participant to perform a travel screening or in most cases, to enter a travel screening in Epic (review below bullet points for details).

CTRC COVID-19 Specific FAQ's and Helpful Information

However, coordinators will still be required to confirm the visit with the participant and remind the participant/visitor to self-screen for symptoms of COVID-19 and not to come to the CTRC if they self-screen positive for COVID symptoms. Confirmation of the visit should not be completed more than 72 hours (3 business days) in advance of the scheduled visit.

Travel screening by CTRC staff at the front desk will remain unchanged and will still be performed as patients and visitors arrive to the unit. Any participant screening positive at the front desk will be asked to wait outside until further evaluation can be performed.

When confirming the visit, remind the participant and visitor (if applicable) to self-screen for symptoms of COVID-19 and not to attend the visit if they screen positive to any of the below criteria. Any participant who self-reports a positive screening to one or more of the criteria listed below must receive clearance from Janette Goins, Director of Nursing, by emailing janette_goins@med.unc.edu before the participant arrives for their appointment. Once additional information has been obtained (i.e., vaccination status, recent COVID diagnosis, documented medical history of another illness, PI or Licensed Independent Provider determines symptoms are not clinically significant for a possible COVID-19 infection), CTRC management will determine whether the visit can continue as scheduled or needs to be rescheduled.

- Cough
- Shortness of breath
- Loss of taste or smell
- Sore throat
- Fever or feeling feverish
- Repeated shaking with chills
- Muscle pain
- Vomiting or diarrhea
- A positive COVID test within the last 10 days (Day 0 is considered the test date) for asymptomatic, mild, or moderate symptoms; or the last 21 days if severe/critical illness or are severely immunocompromised (regardless of disease severity)

Participant and Companion Masks

Per the UNC Health [Universal Mask policy](#), all participants will be given a clean, single use procedure mask and instructed to wear the mask at all times while in the facility. If a companion comes with the participant, they will be given a mask to wear if they do not already have one on. Only one mask per companion is permitted and home-made or cloth masks are acceptable for visitors/companions only.

- A respiratory etiquette station has been created at the entrance to the CTRC waiting room with hand sanitizer, procedure masks and instructions on how to wear the mask.

CTRC COVID-19 Specific FAQ's and Helpful Information

- If a participant does not want to remove their personal mask, they will be permitted to continue wearing their personal mask however the clean, procedure mask must be applied over their personal mask.
- Participants and companions should wear the mask for their entire visit, even when the exam room door is closed.
- Participant and companions may discard the mask upon leaving the facility or take the mask home.
- Facemasks and cloth face coverings should not be placed on young children under age 2, anyone who has trouble breathing, or anyone who is unconscious, incapacitated or otherwise unable to remove the mask without assistance.
- Vendors and others (e.g., UPS, FedEx, LabCorp) entering the CTRC are required to follow the same protocol and always wear a mask while on the premises. To conserve supplies, vendors and others will be provided a UNC Health mask only if they have no mask or face covering; for vendors, home-made or cloth masks are acceptable.
- Participants who are wearing an "N95" or "KN95" should remove their personal mask and don a hospital issued mask. This is because there are many N95's and KN95 on the market that are not made to current standards and can be confused with construction masks which are not necessarily the same as medical N95's.

Patient Care Room Limits

The CTRC Scheduler has been modified as detailed below. Study personnel should continue to schedule visits throughout the day rather than only using morning hours to assist in physical distancing when possible. Until further notice, the following change has been implemented for our patient care rooms/chairs. All other rooms/resources are schedulable without restrictions.

- Six (6) standard exam rooms are schedulable for non-COVID visits, two (2) exam rooms are schedulable for COVID treatment trial related visits

Participant Check-In Process

Participants should be advised to enter the left most outer doors when entering the Burnett-Womack building unless handicap access is needed (far right doors). Signage has been installed in the lobby area to instruct participants on the mask and visitor policies. Participants and companions will be required to perform hand hygiene and don a new mask (participants) at the respiratory etiquette station located outside the entry door before they are permitted into the waiting room. All doors leading into the waiting room will be propped open to decrease touching of door handles.

CTRC COVID-19 Specific FAQ's and Helpful Information

Additional measures that have been implemented in the Waiting Area:

- Sneeze guard located at the front desk will remain until further notice
- Some social distancing floor decals will remain to help remind waiting participants and companions to be mindful of physical distancing during check-in process

Triage Process, Rooming and Reserving Rooms Prior to Participant Arrival

In general, one CTRC team member will be assigned to triage each day. Other nursing staff will assist if available. If not in use, Coordinators are permitted to use an empty triage room to obtain their participants vital sign measurements if trained to do so.

Once the participant has been checked-in and the triage process completed (if applicable), Triage Staff will escort the participant back to the waiting room. Once the study coordinator/research assistant arrives to the CTRC, they will self-assign an available exam or consult room by indicating the required information on the dry erase room assignment board located on the wall in the middle hallway of the unit then escort the participant to the room.

An extended stay room or infusion chair will be assigned by CTRC nursing staff for visits that are considered high intensity (i.e., infusions or other study drug administration, serial PK's) and participants will be immediately roomed by triage staff after the triage process is completed. For visits that require them, the printed Epic labels will be given to the participant.

In the event the participant needs to be consented first, the coordinator will escort the participant back to the waiting room to be placed in line to obtain vital sign measurements in order of the request. The coordinator should also notify the Triage Staff that the participant is ready for vitals.

Rooms cannot be held for a participant who has yet to arrive for their visit unless permission has been granted by the Director of Nursing or the Charge Nurse (special consideration is given to visits that require equipment setup).

Please adhere to your room reservation times so as not to impact others waiting to use rooms.

Exam Room Cleaning and Dry Erase Board

Study coordinators are required to clean patient care rooms after each visit by wiping down all surfaces with provided Sani-Wipes (must wear gloves) including the exam table and high touch surfaces such as keyboard, mouse, and phone (if applicable) and pull new exam table paper at completion of visit. Chairs and tables should be returned to their original locations. In the event time does not permit cleaning a room after use, please notify the Charge Nurse to assist.

CTRC COVID-19 Specific FAQ's and Helpful Information

Coordinators will continue to erase their name from the room assignment board at the end of the visit and after the room has been cleaned.

Participant Checkout Process

Participants should exit the unit through the waiting room. Coordinators are responsible for signing out their participants on the sign-out sheet located at the Front Desk or in the Coordinator Workroom, or by notifying front desk staff of the time of the participant's departure. The sign out time will then be recorded in CRMS by CTRC Staff.

Participants should not exit the unit through the middle hallway leading to the door that states "Authorized Personnel Only" located near the Provider Workroom. Participants can exit the unit to the hospital via the connector (to Old Infirmary) only if they are being escorted by a member of the study team as the door remains locked and badge reader access only.

Appointment Reminder Email

Front desk staff will email appointment reminders a day ahead of a scheduled visit to confirm the visit and to remind participant/companion to self-screen for symptoms of COVID-19. The email will also include the following reminders:

- The coordinator will be requested to confirm the visit and remind the participant/companion to self-screen for symptoms of COVID-19
 - Information on the current visitor policy
 - A documented Epic travel screening is no longer required unless there is a positive participant self-report of any of the criteria listed above
 - Any participant/companion who self-reports a positive screening to one or more of the criteria listed above **must receive clearance from CTRC management for the visit to continue** by emailing janette_goins@med.unc.edu (if not available, the Charge Nurse) **before the participant arrives for their appointment**
 - Once additional information has been obtained (i.e., vaccination status, recent COVID diagnosis, documented medical history of another illness, PI or Licensed Independent Provider determines symptoms are not clinically significant for a possible COVID-19 infection), the CTRC will determine whether the visit can continue as scheduled or needs to be rescheduled
 - Regardless of phone screening, any participant/companion will be screened on arrival to the CTRC
 - Participants will be given a clean, single use procedure mask and instructed to always wear the mask while in the facility
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CTRC COVID-19 Specific FAQ's and Helpful Information

Phlebotomy

Both blood drawing chairs can be used if the need arises. CTRC nursing staff may assist with blood draws when available however priority is given to care of participants with high intensity nursing visits. As a reminder cleaning the area between participants, may add an additional 5 minutes onto the participant's wait time depending on the time of day. As a reference, the average blood draw time from start to finish pre-COVID was 15 minutes on average.

If wait times become too long, coordinators can escort participants to one of McLendon Labs' Blood Collection Centers. The closest center is on the 1st floor of Memorial Hospital at the top of the escalator. McLendon Labs offers the research phlebotomy services for minimal cost. Refer to the studies billing coverage analysis for current pricing and the tip sheets on Research Central for further information on how to use this service.

Blood Volume and Times

Study coordinators should refrain from entering the Phlebotomy Room to inquire about blood draw times and volume. Draw times will be written on the outside of the biohazard bag label and recorded in Epic. Unless a lab requisition was provided to document total volume (e.g., ID group), coordinators should independently determine blood draw volumes by using the tube volume indicated on each tube drawn to determine total volume once the draw has been completed.

Specimen Processing and Storage Facility (Room 1035)

As a reminder, the lab space is a clinical specimen processing lab only. As such, chemicals are not to be used or stored in the lab or other areas of the unit without written permission from the university's Environmental, Health and Safety office. Once approved the Safety Data Sheet must be placed in the binder labeled "SDS" in the lab. There is not a chemical fume hood or biosafety cabinet (BSC) located on the unit.

- The middle table should not be used to process specimens
- Coordinators can use the centrifuge in the Serial Processing Room (1039) when the main lab has reached capacity, however, check with Charge Nurse to verify availability prior to using this space
- Continue to dispose of unused urine in the closest bathroom (amounts > 50 mLs), otherwise urine specimen cups can be disposed of in the red biohazard waste bin after ensuring lid is tightly closed and sealed in a biohazard bag
- Boxes or other containers should not be left on the floor in the specimen processing room to facilitate cleaning by housekeeping
- Follow the CTRC's Lab Etiquette Guidelines and EHS policies when using the area.

CTRC COVID-19 Specific FAQ's and Helpful Information

- No open toed shoes, food or drinks will be permitted
 - Known COVID-19 positive samples cannot be processed in the CTRC lab space
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Processing Specimens

Centrifugation

- Blood samples from asymptomatic participants are expected to present a low risk for infection, but as an additional precaution, it is recommended to wait as long as possible before opening the lid of centrifuge after centrifugation (e.g., up to 20-30 minutes) has been completed to allow aerosols to settle.
- After centrifugation, individual buckets should be opened behind the benchtop shield only.
- Observe routine safety precautions including visual inspection of tubes before removing samples from buckets to ensure tubes are not broken.
- Respiratory samples are more high risk and are not to be processed in the CTRC as they require a biosafety cabinet.

Minimum Personal Protective Equipment (PPE)

- Gloves
- Mask
- Benchtop shield
- Lab coat or use of disposable arm sleeves (provided by CTRC, located in a labelled drawer in room 1035 or 1039)
- A mask and eye protection (recommended) must be worn when processing a sample behind a benchtop shield

COVID-19 known positive samples cannot be processed in the CTRC. Currently the IBC has restricted processing (which includes aliquoting) of potential and confirmed COVID-19 samples to BSL-2+ containment, requiring use of a Biological Safety Cabinet (BSC) and additional PPE and procedural/administrative controls such as SOP's and training.

Specimen Storage & Transport

When transporting specimens in the CTRC, samples must be placed in a sealed container with a biohazard label. Urine samples should be double bagged. Specimens from COVID units can be stored in the CTRC if they are properly marked and maintained under a double lock. Note per University EHS, COVID-19 positive respiratory samples must be transported by hand, samples should not be sent via the tube station. Contact McLendon Labs at 984-974-2361 for the most up to date information on transport of COVID positive respiratory samples.

CTRC COVID-19 Specific FAQ's and Helpful Information

Respiratory Samples

CTRC leadership continues to follow University EHS and Hospital Epidemiology's current [policies](#) to determine what type of respiratory samples can safely be collected from asymptomatic patients and what cleaning procedures will need to be performed once the visit is completed. As these guidelines change periodically, contact janette_goins@med.unc.edu for approval prior to obtaining these types of samples in the CTRC.

Symptomatic Participants and Companions

Any participant who screens positive at check in will either be asked to wait outside the Burnett-Womack building or immediately be placed in an exam room for isolation with the door closed. The participant will be placed on [special airborne contact isolation](#) which requires specific PPE when entering the room and additional screening will be completed before determining if the participant needs to be sent to their primary care provider for further evaluation. COVID-19 testing is not completed in the CTRC at this time.

Hand Hygiene and Glove Usage

Frequent hand hygiene, either by washing or the use of alcohol-based sanitizer, is an effective way to prevent the spread of pathogens in the healthcare setting. Please review the CDC's "[Five Steps to Wash Your Hands the Right Way](#)" and view the [CDC video on handwashing](#).

- All individuals should thoroughly wash their hands or use provided hand sanitizer:
 - Before entering or when exiting the CTRC
 - Before and after handling their facemask or eye protection
 - Before interacting with research participant and immediately after completing the visit
- If hand washing is not an available option, use hand sanitizer to disinfect hands. Hand sanitizer is located throughout the CTRC.

According to the CDC, gloves are not necessary for general use and do not replace good hand hygiene. Hand hygiene should be performed before and after using gloves for tasks where they are indicated. Gloves should be changed when moving from one task to another to avoid cross contamination. Please do not wear gloves when charting, opening doors, talking on phones, etc. Even when wearing clean gloves, the perception is that the gloves are "dirty."

CTRC COVID-19 Specific FAQ's and Helpful Information

Practicing Physical Distancing

While most all maximum occupancy restrictions throughout the CTRC and on campus have been removed, the following areas continue to have designated maximum allowable occupancies as described below.

- Conference Room – maximum of 6 employees during meal breaks from 11:30 am – 1 pm
 - Nourishment Room – maximum of 1 employee at any given time due to the size of the room
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Coordinator Meal Breaks

Meal break or consumption of food will not be permitted in the Coordinator Workroom at this time. However, the small refrigerator and microwave are still available to store lunches and reheat food. The conference room has limited seating available on a first come, first serve basis, and is reserved for meal breaks between the hours of 11:30 am – 1 pm daily. The additional guidelines should also be observed:

- Individuals are encouraged to eat meals outside when possible
 - If common areas such as break rooms and conference areas, etc. are used for meals, the person using them must wipe down surfaces using 70% ethanol or equivalent solution after use. Disinfecting wipes are available in the CTRC Conference Room for you to use.
 - Physical distancing of 6 feet should always be observed during meal breaks when masks are off.
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Conference Room (Workspace, Meal Breaks, Trainings)

The conference room, located in room 1045, can be used as additional workspace for study personnel during the hours of 7:30 am – 11:30 am, and 1 pm to closing, and for meal breaks between the hours of 11:30 am – 1 pm.

The conference room can also be reserved for meetings or trainings, and when reserved, a sign will be posted outside the room to notify staff to remove belongings.

Research Participant Snacks and Nourishment Room

Coordinators and research staff can continue to obtain their own snacks and water or ice from the Nourishment Room located in 1022. Study personnel and CTRC staff should perform hand hygiene when entering the room before touching any surfaces including the refrigerator door and ice machine.

CTRC COVID-19 Specific FAQ's and Helpful Information

Clean Utility Room

Per Infection Control guidelines, only CTRC staff can access the Medication and Clean Utility Room. Please see CTRC staff for any needed supplies.

Linen and Paper Products

Disposable paper products should be used as much as possible. Paper gowns, paper half sheets and pillowcases will continue to be stored in the exam rooms in closed drawers. Linen will only be used in a limited capacity (e.g., extended stay rooms with beds).

Tours of the CTRC, Monitor and Site Qualification Visits

Tours can resume however they should be scheduled in advance with the Director of Nursing and when possible, should be scheduled in the afternoons Monday – Thursday, or on Fridays when the unit is less busy. Monitors and other personnel must abide by all current University COVID guidelines including masking requirements.

Effective April 12th, 2022, UNC Health's COVID-19 immunization requirement shall apply for research monitors who visit the CTRC in addition to designated UNC Health facilities, including the IDS Pharmacy. Research monitors must attest to being fully vaccinated prior to visiting the CTRC. Use of a mask is not an acceptable alternative to receiving the COVID-19 vaccine. For research monitors who are not vaccinated or who have been exempted from vaccination by their employer, the only alternatives are to send a delegate/substitute or to conduct the work remotely with assistance from the site-based study team. In addition, research monitors should reschedule their visits to the CTRC if they have symptoms of an infectious disease or exposure to communicable diseases per UNC Health policy. Research monitors with signs or symptoms of an infectious disease or exposure to communicable diseases should be cleared by their occupational health department or local physician before visiting or working at the CTRC. [COVID-19 Immunization of Healthcare Personnel](#) for additional information on the policy.

Once a research monitor has completed the online forms as describe in the policy above, the study contact initiating the process will receive email notifications for tracking purposes and to allow planning for the associated visit. For visits that will occur in the CTRC, the study contact must forward PDF of the attestation to Janette Goins at janette_goins@med.unc.edu. Research monitors will not be allowed to visit the CTRC if they do not have an attestation on file for that visit. The email notification for the Confidentiality Statement will also include a copy of the completed form in PDF format which may be filed or distributed as needed to facilitate visit requirements.

CTRC COVID-19 Specific FAQ's and Helpful Information

Patient Transportation

Participants that require assistance may continue to request transport from the UNC Medical Center to the CTRC via Guest Services. Participants should request transport to the CTRC's Reception Desk by stopping by the Women's and Children's Hospital Guest Services Desk. Guest Services will escort the participant to the 1st floor of Burnett-Womack using the back entrance through the tunnel connector from the Old Infirmary Clinic. Contact Guest Services at 984-974-0709 for more information.

Internal Route from Memorial Hospital to Burnett-Womack

Research Participants and CTRC users may utilize the internal route through Memorial Hospital by following the posted signs. This route begins at the top of the escalators near the Blood Collection Center and Pre-Care, through the Old Infirmary Clinic, past the hospital's mail room and eventually to the back door of Burnett-Womack. Please remember badge access is required to exit from the Old Infirmary into the Burnett-Womack building and participants will need to check-in at the CTRC Reception Desk before starting the visit.

Additional Information and Resources

- [Environmental, Health and Safety COVID-19 Information for Employees](#)
- [Carolina Together](#)
- [UNC Health's COVID-19 Updates and Resources](#)
- [Clinical Research Support Office \(CRSO\)](#)
- [Office of the Vice Chancellor for Research: COVID-19 Guidance and Resources](#)