Clinical Research Social Distancing and Infection Prevention Guidelines

On-premises clinical research of non-COVID protocols
Guidance version May 18, 2020

Overview: The response to the COVID-19 epidemic at Duke, like many of our national peers, can be categorized into phases which mimic those used by public health and state officials:

- **Shelter in Place:** Ramping down of non-essential Tier 3 research activities and execution of the shelter in place order; on-going performance of essential (Tier 1 activities and Tier 2 follow-up) in-person research studies while moving all other activities to remote/virtual; pause of Tier 2 in-person enrollment; tracking of operational changes to studies; ramping up of COVID-19 research studies; maintaining research activities via remote/virtual activities.

- **Phase 1:** phased, monitored restarting of on-premises, externally funded Tier 2 enrollment activities that were paused due to requirement for in-person engagement and can be completed during clinical care visits (do not require separate participant visit); continue on-going remote/virtual activities and focus on hybrid model limiting in-person contact; continue teleworking for all non-in-person activities.

- **Phase 2:** phased, monitored restarting of on-premises, externally funded Tier 3 enrollment activities that were paused due to requirement for in-person engagement and can be completed during clinical care visits (do not require separate participant visit); continue on-going remote/virtual activities and focus on hybrid model limiting in-person contact; continue teleworking for all non-in-person activities.

- **Phase 3:** Phased, monitored restarting of remaining Tier 2 and Tier 3 in-person activities, including community-based studies, internally funded studies, and studies that cannot be completed during clinical care visits; continue on-going remote/virtual activities and focus on hybrid model limiting in-person contact; continue teleworking for all non-in-person activities.

- **Phase 4:** Phased, monitored return of staff to the work-place and conversion of remote/virtual activities to in-person.
The following guidelines will describe practical application of clinical research strategies to minimize COVID-19 exposure for our patients, research participants, faculty, and staff as we return to increasing in-person clinical research operations. Duke faculty and staff should refer to the “Duke Guide for Returning to the Workplace” document for additional guidance.

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Phased Re-entry for Studies
To optimize our ability to safely practice social distancing with our colleagues and research participants, and to ensure adequate availability of PPE, hand sanitizer, and disinfectants, we will gradually phase the resumption of in-person research activities over 3 phases. The progression from one phase to the next will be contingent on stable conditions in the health system and the local and state-wide community. The dates provided are projections for the phases of returning to clinical research activities and may change. The opening of each phase will be communicated to the clinical research community in advance, as will any delays or changes in the projected dates.

- On June 1, 2020, Phase 1 of return to research activities, as detailed above, will begin. This mirrors the public health 3-stepped approach beginning 2 weeks following clinic re-entry. Please note, as described below; any research activities that were converted to remote during the time of COVID-19 should continue to be performed remotely and teleworking for staff
should continue except the limited periods when in-person research activities are required.

- Phase 2 projected date is June 15, 2020
- Phase 3 projected date is July 15, 2020
- Phase 4 does not have a projected date, this will follow federal, state, local and University guidance

 Managers must approve the return of staff to clinical research activities, which will be provided to the SOM. Return of select staff to clinical research activities does not equate to return to extensive usage of administrative spaces. Administrative spaces will open as per the larger coordinated SOM and Duke University efforts. Until administrative spaces are opened, they cannot be used for clinical research administrative activities, which will need to continue virtually.

 We recognize that some areas of Duke have unique workflows that may allow for safer resumption of in-person activities earlier than their Tier or category planned return. CRU leaders can contact: somclinicalresearch@dm.duke.edu to discuss these scenarios.

 Only those personnel who have been specifically cleared to return to work should return to campus and DUHS; time on campus should be limited to the time required for in-person and related clinical research study activities. All other related research activities should be completed at home. School of Medicine and School of Nursing clinical research faculty and personnel will receive notification when their study has been approved to resume on-site activity. If you believe your study should be approved to resume such activities and you have not received a notification, please contact somclinicalresearch@dm.duke.edu.

 **General Employee Workplace Guidance**

 Staff members who have been instructed to return to work on-site and have concerns about doing so due to a medical condition that places them in a higher risk group, those who are pregnant, or those who wish to seek ADA Reasonable Accommodations related to Returning to the Workplace should visit the Disability Management System website (access.duke.edu/employees) or call 919-684-1424. Additional information on COVID-19 risks in the Healthcare setting are provided by DUHS here.

 After your studies have been approved to resume in-person research activities, you will receive a survey link to register for daily symptom screening. You will be required to complete a symptom screening every day
before coming onsite. This screening is provided by Duke Employee Occupational Health and Wellness (EOHW). If flagged by the screening checklist, you must contact the COVID-19 hotline at 919-385-0429, as well as your direct supervisor, and act on their instructions.

☐ If you have tested positive for COVID-19, have been referred for testing by EOHW or are awaiting test results, you must notify your supervisor immediately, and you may not come to work for any reason until approved by EOHW.

☐ Face covering must be worn in all Duke facilities, including leased buildings, until further notice. When eating, drinking, alone in a private office or going to the restroom, face masks can be removed and stored with exterior side down on a paper towel or in a paper bag. Disposable masks will be provided. You are expected to use only one clean mask per day. Additional details on masking requirements and caring for your mask can be found here as well as within the Duke Guide for Returning to the Workplace.

What to Expect When I Arrive at Work?

☐ When entering DUHS hospital or clinic buildings for the first time each day, you must enter through the main entry way to be screened. After then, you may enter and exit through adjoining buildings if you have approved access. You may not enter DUHS hospital or clinic buildings through any adjoining buildings or access points if it is your first time entering for the day.

☐ At the entrance to the hospital or clinics, you will need to show your ID badge and be screened. You will be asked questions regarding potential COVID-19 exposure and symptoms and will have your temperature taken using a touchless device.

☐ You will receive a face mask. Additional guidance on wearing and caring for your facemask is included below and can be found in the Masking Guidelines from the Duke Guide for Returning to the Workplace as well as the DUHS “Getting through the Day with Your Mask” document, which are linked here.

☐ Additional guidance on disinfecting rooms and PPE are available within DUHS “PPE and Frequently asked Questions” document linked here.

☐ You should maintain social distancing of 6 ft, including when you are in breakrooms or administrative rooms with your colleagues. Detailed guidance from DUHS should be reviewed: How To Safely Share Meals with Others at Work During COVID-19 Pandemic.

☐ Practice both frequent hand-washing and environmental cleaning, which involves disinfecting workspaces at the beginning and end of each day and more frequently for high-touch surfaces. Additional guidance can be found in the DUHS “PPE and Frequently asked Questions” document as well as the
“Keeping Yourself and Your Team Members Safe” document. Additional information specific to study visits is included in the “Visit Hygiene and Distancing Procedures” section below in this document.

Minimize Potential for Exposure as Duke Returns to In-Person Clinical Research Activities

Retaining Virtual Activities
During the shelter-in-place phase, we have learned to efficiently operate virtually in a number of different ways. **For the first 3 phases of return to clinical research activities, these virtual activities must continue.** CRU directors and Research Practice Managers will work with PIs and study teams to develop hybrid models for returning to clinical research activities, utilizing virtual and remote activities when and where possible. Specific guidance will be found in multiple sections below.

- All studies with pre-COVID-19, IRB-approved virtual or remote consent, monitoring, and/or study visits should continue to perform these activities remotely.
- All studies with consenting and study visit activities that were converted from in-person to remote due to COVID-19 are asked to continue those practices as well. Those changes constitute a platform change under IRB COVID-19 memo (March 11, 2020), thus an IRB amendment is not required at this time, though internal tracking for future reporting is required.

Assessing for and Routing Participants Who Report Symptoms

- **Establish multiple screening points** to assess participants for COVID symptoms and exposure. Research staff will have access to the [Screening Job Aid in Maestro Care](#) for Duke patients (directions accessible here), and a paper version is available here for research participants who are not DUHS patients or when the Screening Job Aid is not easily accessible via Maestro Care
  - **At scheduling** (on phone or online);
  - **On pre-visit calls** (described below);
  - **Upon arrival** (front entrance; managed by DUHS)
  - **At check-in** (front desk or presentation to research team member).

- If participant screens positive, have participant call the **COVID patient hotline (919-385-0429, option 2)** and **COVID triage** to direct adult, pediatric, or obstetrics patients to the right site of care – including tent testing sites, ED, Respiratory Care Centers, or referral to PCP for Video Visits and Home Monitoring depending on the severity of symptoms.
COVID-19 screening procedures that may be mandated by the health care system in which a clinical trial is being conducted do not need to be reported as an amendment to the protocol even if done during clinical study visits unless the sponsor is incorporating the data collected as part of a new research objective.

General Social Distancing

- Complete entire research visits via video visit or telephone encounter whenever possible.
- Complete as many parts of a research visit or preparation for a research visit via video visit or telephone encounter as possible.
- In person research visits should be limited, with as much done virtually prior to the in-person visit as possible.
- Encourage participants to come to appointments alone whenever possible (e.g., add to on hold messages, appointment reminders, phone screening conversations).
  - Current DUHS policy limits patients in the ED or clinic to one visitor over 12 years old.
- Spread out research visit start times to avoid large volumes of participants at check-in and in waiting rooms at the same time.
- Telephonic pre-chart any pre-visit work for the next day’s visit to avoid and/or limit what needs to be done after participants arrive, including calling participants ahead of time to complete medication reconciliation and other tasks.

Lab And Leave: For LABS, Non-COVID+ Participants With Ancillary Services

- Effective April 27, 2020, several clinic locations in Durham and Wake Counties will begin providing “Lab and Leave” phlebotomy services for adult patients.
- Study Investigators and clinical research teams should create a lab & leave process in coordination with clinics and ancillary labs whenever possible. Practices may include:
  - Allowing participants to wait in their car (rather than a waiting room) until the time when their labs can be drawn or other services rendered.
  - Designating a single coordinator for your team or unit who will work with a lab, core or service. e.g., delivering collection supplies and bringing in participants.
In-Person Study Visits

As we return to clinical research in-person activities amid continuing COVID outbreaks, we should initially function assuming every research participant could be COVID+ or COVID exposed. All best practices for Infection Prevention and flow should be followed for each participant.

☐ Whenever possible, conduct remote study visits (see Remote guidelines).

☐ When not possible to conduct entire study visits remotely, conduct as many aspects of the visit or data collection remotely as possible and follow the guidelines below to ensure safety during in-person activities.

☐ Every effort should be made to engage research participants in discussions of safety and to build trust in their partnership as a member of your research study and the Duke community.

  o Prior to their visit, participants must be made aware of both the risk of COVID exposure they may encounter during on-premises, in-person study visits, and the safety precautions taken to keep them and other patients and participants safe. This should be done by providing the Clinical Research Participation During COVID-19 Guide to participants before their visit.
    ▪ Use only this official document which has been vetted and approved by Duke University.

  o Study coordinators and investigators should be prepared to discuss safety precautions and participation options, including continuation as planned, visit deferral, and withdrawing from the study.

  o Participants should be given ample time (days or weeks) to consider the risks and precautions prior to their scheduled visit.

☐ When agreeing to come in for a research visit, participants must acknowledge an understanding of these risks and planned compliance with Duke’s safety measures.

☐ Participants who are unwilling to comply with DUHS safety standards including screening and PPE, should have their study visit deferred until either they are willing to comply, or such safety standards are no longer necessary or required by DUHS. Such deferments should be tracked via note to file.

Visit Hygiene and Distancing Procedures

Below are measures that can be taken to decrease risk to staff and participants. We encourage research teams to integrate as many safety measures as possible,
particularly during this early period when community cases of COVID are expected to increase

- Have participants call the front desk or research team member to check in (consider a dedicated phone number for clinics with phone trees) and wait in the car until called for their appointment. Or, if facility design allows, consider checking in via tablet in the parking lot as cars and participants arrive.
  - Clinic front desk and research staff should coordinate to call participants with enough time to get from car, through screening, and to front desk but not wait in waiting room.
  - Where waiting is required, instruct participants to follow clinic procedures including masking and hand hygiene upon entry and 6+ feet distances to facilitate social distancing.
  - When checking valid picture ID, participant holds license while staff views ID.

- All participants and visitors are masked upon entry to the facility and instructed to keep mask on during their time in the facility unless instructed to remove the mask by their provider or staff. This includes while waiting in the exam room.

- Upon rooming, if layout of the room isn’t conducive to 6 foot distance between staff and participant, consider taking participants cell phone number to conduct appropriate portions of intake via FaceTime or phone from outside the exam room.

- Check processes and establish observations for hand hygiene for participants and all staff and providers going into a room, before and after touching a participant and after leaving a room.

- Confirm process and conduct observations of fully wiping down all equipment in room, including commonly touched surfaces (doors, sink, chairs, beds) and any equipment touched by staff or participant.
  - Clean and wipe down each visit room between participants.
  - Clean all equipment—including blood pressure cuffs, pens, computers, keyboards, mouse, door handles, etc.—before and after use.
  - Wipe down shared areas and commonly touched surfaces (doors, exam room furniture and beds) with Oxivir wipes once per hour.

Consenting Procedures and Research Documentation
Written consent is still required for participation in research studies in accordance with usual regulations. Some concessions to the usual process for obtaining written consent have been made during the COVID pandemic.
Perform remote consent (eConsent, phone consent, or consent using virtual platforms like WebEx and Zoom) whenever possible (Remote guidelines). Per DUHS IRB March 11 memo, a change from in-person to remote consent constitutes a platform change and does not require an amendment at this time. Such changes should be internally tracked for such a time when further documentation and reporting is required.

A waiver of documentation of consent or a waiver or alteration of consent may be considered under specific circumstances and would require an IRB protocol amendment via the usual process.

For participants who are being asked to participate in on-premises study visits, acknowledgement and review of the potential risk for COVID exposure as well as the screening and safety precautions taken to minimize exposure should be part of the consent conversation. Follow procedures described above by providing the approved Clinical Research Participation During COVID-19 guide to potential participants in advance of the consent conversation.

Resources

- Duke Guide for Returning to the Workplace
- DUHS document library
- Research FAQ
- Remote guidelines
- For participants:
  - Document: Clinical Research Participation During COVID-19
  - Website: https://www.dukehealth.org/covid-19-crisis-guidance-research-participants
- For Screening:
  - Screening Job Aid in Maestro Care
  - a paper version
  - Duke Primary Care guidelines
- PPE and Masking
  - DUHS PPE FAQ
  - Outpatient management of asymptomatic patients
  - Duke Guide for Masking
  - Getting through the Day with your Mask
- Workspace safety
  - DUHS PPE FAQ
  - Duke Guide for Returning to the Workplace
  - How To Safely Share Meals with Others at Work During COVID-19 Pandemic.
  - Keeping Yourself and Your Team Members Safe