CHOP Research Institute FAQs for Clinical Research during the Coronavirus Pandemic

Updates to the previous version from February 14, 2022.

GENERAL QUESTIONS

Which studies can resume research activities?

All research studies can resume activities.

What is the staffing level allowed for research groups?

As of June 4, 2021, the Research Institute moved into Stage 4 staffing levels at 100 percent capacity. Employees who are not location critical and have remote capability may continue AWA as advised by their manager.

Where is FDA guidance available on conducting clinical trials during the pandemic?

For additional information, the U.S. Food and Drug Administration (FDA) issued a guidance for industry, investigators, and institutional review boards conducting clinical trials during the COVID- 19 pandemic. Please see: https://www.fda.gov/regulatory-information/search-fda-guidance- documents/fda-guidance-conduct-clinical-trials-medical-products-during-covid-19-pandemic.

Where can I find more information related to NIH Applicants and Recipients?

Please use the following link to review current NIH guidance related to flexibilities in grant deadlines, FAQs, and resources: https://grants.nih.gov/grants/natural_disasters/corona-virus.htm

RETURNING TO WORK

What should someone do if they don't feel well or develop symptoms concerning for COVID-19?

Anyone with symptoms should NOT come to work, and those who develop symptoms at work should go home and/or seek medical care. Teams should develop sick relief protocols to accommodate this contingency. A new Contact Tracing Self-Service tool has been created for vaccinated employees to use.

Affected employees should consult the CHOP Bioresponse page for specific testing and return to work guidance.

What should someone do if they live in a household with or if they have had a high-risk exposure to someone with COVID-19?

Please consult the CHOP Bioresponse page for specific testing and return to work guidance after COVID-19 exposures.

You may contact the CHOP Bioresponse Hotline at 1-800-7220-7112.

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Is it safe to come back to work via public transit?

Research staff have been traveling safely to work via public transportation. Public transportation is operating at full capacity with masking required. For more information on public transit and safety during the pandemic, please see the CHOP Bioresponse page and SEPTA Reopening Guide.

I am having challenges receiving packages I have ordered for my research study. Where can I pick up my mail?

Mail and packages for Roberts staff are now being delivered each floor at Roberts.

For more questions about mail delivery or tracking packages, please reach out to Christine Tillson at Tillsonc@chop.edu.

ACCESS TO PPE / RESEARCH SAFETY

How do we obtain PPE for clinical research personnel?

PIs should order PPE for both wet lab and clinical research from COUPA at this time. PPE should not be taken from clinical teams or arenas. Research Safety does have a limited number of L/XL/XXL gloves still available. Please contact ResearchSafety@chop.edu with questions about obtaining PPE.

For teams that need N95 masks for research staff to use during subject interactions, there is a limited supply available from the Clinical Research Support Office. Please email ClinResearchQuestions@chop.edu to request masks.

Questions about disinfecting wipes should be directed to Supplychain@chop.edu.

***What PPE should I be wearing on campus?**

For complete up to date guidance on masking and other PPE policies, please view CHOP's PPE playbook.

Please note that as of April 19, 2022, CHOP is requiring masking in all publicly accessible areas including lobbies, elevators, and cafes. This includes in the Roberts building and in publicly accessing bathrooms and hallways on the 4th floor of Roberts.

Do I need fit testing for a mask to wear in clinical areas? Do I need an N95 mask?

Surgical masks should be worn in clinical areas, but these do not require fit testing. You do not need an N95 mask for routine research procedures performed in clinical areas. N95 masks are indicated for patient interactions that involve aerosol-generating procedures. For more information on PPE, please see https://at.chop.edu/osmo/eop/bioresponse.

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WORKPLACE CONDITIONS

Is the air circulation in Roberts safe?

After review of FGI guideline, ASHRAE recommendations and standard building codes for a medical building, Facilities and Management has confirmed with Infection Prevention and Control that the air circulation in Roberts is safe.

The 4th floor of Roberts is shared testing space. Is there additional guidance on the use of that space?

Researchers may book testing space on the 4th floor of Roberts. At this time, coordination between groups on the 4th floor is the responsibility of the individual PIs and group leaders.

How many and how long can people spend in each assessment room with the door closed? Some of our studies require at least two study staff plus a child and their parent.

The study staff should work to ensure physical distancing in these rooms whenever possible. This may require using a larger assessment room and attention to study staff position within the assessment room. There are no time limitations for the duration of the research visit.

How long will it take to return to normal?

Please visit the @CHOP "New Normal" site for up to date information on CHOP requirements for working on campus and stages of adjusting COVID restrictions. Research teams should align with CHOP clinical policies on PPE use and physical distancing when working on campus. Please refer to https://at.chop.edu/osmo/eop/bioresponse for additional guidance.

Will Environmental Services perform more cleaning and disinfecting in research areas?

Yes. To allow for cleaning between use, personnel should not share the exact same workspace (i.e. desk) within a single day. Separate work surfaces must be available if days are split between workers or cleaned appropriately between use.

What if we have concerns returning to work in-person?

PIs should meet with staff members individually to assess challenges or concerns with returning to non-remote work.

RECRUITING AND SCREENING

What screening is required prior to bringing research participants to CHOP?

The requirement for screening research participants prior to coming to campus is similar to the screening for patients coming in for clinical care. Research staff are responsible for confirming that

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screening has taken place for research visits occurring in conjunction with a clinical visit and performing screening for research only visits. If the research only visits will occur in a CHPS unit, the research team is responsible for notifying CHPS that the screening has been completed and the results of the screening.

Subject checklists have been revised regarding research screening and can be accessed here.

Do study teams need to complete the Subject Checklist, and if so, what do they do with the checklist once completed?

No, the Subject Checklist no longer needs to be completed for each subject enrolled. The checklist should be used as a guidance document for study teams to complete screening of subjects. Please note that some form of screening should be done and that some groups that support research visits (e.g. CHPS) may require that certain screening questions are asked prior to the visit. The Subject Checklist can be used as a guide to ensure that subjects are appropriately screened before coming to campus. The latest version of the Subject Checklist can be found here.

When is the best time to complete the screening checklist? Can a research team complete it multiple times for the same subject? Can any questions be changed or added?

The study team should complete the screening before the subject arrives on campus, usually within a day or so before. You may complete the screening multiple times (as needed) but the most recent responses should be used to determine visit eligibility.

If a subject screens positive on the screening checklist does that mean that the visit has to be rescheduled?

No. In alignment with CHOP ambulatory care guidelines, a positive screen on the checklist no longer means that the visit must be rescheduled. Rather, a positive screen means that a determination should be escalated to the PI or a physician level team member to determine if the risk of potential exposure outweighs the benefit of the onsite visit. If bringing in a subject/parent that screens positive, the research team needs to ensure that research staff are comfortable with the visit, that research staff have access to and are donning appropriate PPE, and that all units/teams where the subject will be seen are comfortable accommodating the visit.

Who issues approval for the Division/Department/Labs listed on the Subject Checklist, and how is approval documented?

The person issuing approval will vary by group, but it should be someone with authority to confirm that there are resources available and that the appointment can be scheduled. Documentation of approval, such as an email or a note to file including who issues the approval and the date/time the conversation took place, should be filed with the Subject Checklist in the study source documentation.

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STUDY VISIT RELATED QUESTIONS

Are we permitted to conduct face-to-face infant evaluations since they cannot wear masks?

Yes. Face-to-face evaluations with infants may be conducted. PPE guidance for research study subjects parallels that for clinical patients; please see the Bioresponse page for additional guidance.

Can SARS-CoV2 positive subjects/parents be consented in person?

Yes. Consent forms can be brought into and signed in a research subject's room if the subject, parent, or legally authorized representative is positive for SARS-CoV2 as long as the research team member performing the consent dons the appropriate PPE and is comfortable conducting in person consent. Research teams should ***never*** *ask SARS-CoV2 individuals to leave the room to sign consent. Please ensure that the consent process being used is consistent with the IRB approved consent plan for the study.*

Are there travel restrictions for Monitors/Trainers?

Study teams will need to complete the Monitor/Training Checklist prior to having the monitor/trainer come to CHOP. This checklist, which can be found here, should be completed on the day before the visit but may be shared with the monitor/trainer ahead of time to ensure that proper safety measures can be taken in advance of their visit to CHOP.

Monitors/trainers need to follow local/state requirements when not at CHOP. Visiting CHOP is considered an essential activity and can take place.
Monitors are currently considered visitors and not contractors at CHOP. Monitors are strongly encouraged, but not required to be vaccinated.

Please note that those coming to CHOP also need to complete the REDCap COVID screening survey before coming to CHOP campus: https://redcap.chop.edu/surveys/?s=WNPHXMHC9A

What monitoring visits are currently permitted at CHOP?

Onsite monitoring visits are permitted for all trials resumed as of Monday 6/29/20, as long as CDC and PA Department of Health guidelines are followed. Remote monitoring is encouraged whenever study-related data and materials can be securely reviewed electronically.

Monitors also need to be screened for symptoms prior to their visit consistent with how study subjects are screened.

Additional requirements for monitoring within the Investigational Drug Service (IDS):

- *Two monitoring visit slots will be available daily (8:00 am and 10:00 am). Teams may reserve a 2-hour slot if the monitor confirms that a longer visit duration is required but visits cannot exceed 2 hours;*
- *Up to 2 monitors at a time will be permitted in IDS pharmacy for each study visit. Guests must remain in the monitoring area at all times to comply with physical distancing requirements;*

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- *A member of the study team must escort the monitor(s) to and from IDS Pharmacy;*
- *Please see the JOB AID: Scheduling Monitor Visits in IDS Pharmacy for more information on the scheduling process.*

For more information on monitoring visits with IDS, please see: https://at.chop.edu/sites/pharmacy/quick-links/investigational-drug-service-(ids)/site-visits

If you have additional questions related to monitoring visit permissibility, please reach out to ClinResearchQuestions@chop.edu

Can Site Initiation Visits (SIV) occur at CHOP?

Yes, SIV may occur starting on June 29, 2020, concurrent with initiation of new research visits.

Can research iPads be used during this time if they are appropriately sanitized prior to and following use?

Yes, research iPads may be used.

Are we permitted to invite research participants for in-person visits who reside out of state? If federal restrictions are lifted for international travel, is it permissible to invite a family to come to CHOP for a research visit if they live outside of the U.S. (e.g., we have several participants who reside in Europe who are a part of a longitudinal study of a rare genetic condition).

Yes, out of state/country research participants may be enrolled in accordance with Federal/State guidelines. Study teams need to complete the Subject Checklist for screening prior to each subject visit and ensure that the study subject and caregiver(s) have adhered to appropriate physical distancing and masking.

If you have additional questions related to visit permissibility, please reach out to ClinResearchQuestions@chop.edu

What about research that occurs in the Emergency Department? We don't have "scheduled" visits.

Research in the ED may take place. Research Coordinators can conduct research activities including interacting with patients and families and entering rooms (including those with aerosol generating procedures as long as they are wearing an N-95 mask for which they have been fit tested and eye protection).

For questions related to research in the Emergency Department, please contact Fran Balamuth, MD, PhD, BALAMUTHF@ chop.edu or Marlena Cook COOKM6@ chop.edu.

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My study involves MRIs/Radiology services. Can I schedule subjects to come in at this time?

There is currently a backlog for subjects coming in for clinical MRIs, which may limit the availability of these resources. It depends on which MRI resource is needed. MR4 is a dedicated research MRI open for research Monday-Friday 8am-10pm.

The Department of Radiology would like to reiterate its dedication to furthering research. To that end, their resources are available for scheduling outside normal business hours to assist our research initiatives if needed. Opportunities exist to scan patients earlier or later in the day, as well as on weekends with staff available to support. What this entails, however, is a closer collaborative effort between the researchers and the clinical staff/leads/managers.

If PIs need to discuss or clarify any potential issues, please feel free to contact the Department of Radiology: Tim Roberts, PhD, Vice Chair for Imaging Research: robertstim@chop.edu
Savvas Andronikou, MBBCh, PhD, Vice Chair for Clinical Research: andronikos@chop.edu

What if I have questions about the Center for Human Phenomic Sciences (CHPS) Studies?

Please see the CHPS Homepage for CHPS specific FAQs.

Is there any guidance on billing for concurrent research and clinical procedures during the pandemic?

Clinical Trial Finance Management (CTFM) guidance is to schedule research encounters as detailed in clinical trial budgets approved by the CTFM. If there are study-specific questions related to standard of care vs. research activities approved in a budget, please contact the CTFM budgeting team at CRAnalyst@chop.edu

I have a question not covered in the FAQs about clinical research. Whom do I contact?

Please email ClinResearchQuestions@chop.edu for questions related to the clinical research ramp-up. This inbox is monitored daily, and we will respond as soon as possible.