**GENERAL QUESTIONS**

Which studies are able to resume research activities?

*All Research studies are able to resume activities.*

What is the current percent of staffing 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.*

Is CHOP planning to modify research activities?

*Since spring 2020, we have learned more about how SARS-CoV-2 is spread and effective ways to mitigate transmission. Employees at CHOP have very effectively implemented proper PPE use and physical distancing in the workplace. Our CHOP data demonstrate that these mitigation procedures have allowed us to conduct research safely for both staff and study participants. The Research Institute’s return to research task force, in collaboration with the Bioresponse team, is continually monitoring virus transmission in the region and on campus, and they will continue to update guidance on allowed research and the FAQs as needed.*

Can research home visits be completed at this time?

*Yes, research home visits can be completed provided the following criteria are met:*  
- PPE use by both CHOP staff and participants interacting with the research team and hand sanitizing procedures as indicated on the CHOP Bioresponse page  
- The family is agreeable to the visit  
- Research staff are available and willing to perform the visit.

Where is FDA guidance available?


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/coronavirus.htm*
CHOP Research Institute FAQs for Clinical Research during the Coronavirus Pandemic

RETURNING TO WORK

Are you testing everyone for COVID-19 as they return to work?

No. Only those with symptoms or with concerning exposures will be tested, according to the latest CHOP Bioresponse policy. Staff should start their day by completing the Daily CHOP Check-in Tool. This tool consists of a brief survey of symptoms for an employee to review prior to coming to work on-site each day. Early identification of symptoms remains a critical piece of preventing transmission of SARS-CoV-2.

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. Affected employees should alert their manager and contact the COVID hotline/Contact Tracing Center hotline: 800-722-7112, Press Option #1.

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 follow the guidance on the CHOP Bioresponse page for guidance on quarantining and returning to work after COVID-19 exposures.

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

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 being delivered to room 2160 at Roberts. Please be sure to regularly check this room. More information on mail delivery across campus can be found here: Mail Delivery Announcement.

For more questions about mail delivery or tracking packages, please reach out to Christine Tilson at Tillsonc@email.chop.edu.
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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. ResearchSafety does have a limited number of L/XL/XXL gloves still available. Please contact ResearchSafety@chop.edu with questions about obtaining PPE.

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

How do we obtain PPE for research subjects?

Masks are available for research subjects and those visiting CHOP. Masks can be picked up at the welcome/check-in desks at ARC, Colket & Roberts.

* What PPE should be worn? How do we return to work safely?

VACCINATED CHOP PERSONNEL

Fully vaccinated employees who voluntarily disclose their vaccination status may choose to do the following in areas not accessible to patients and families:

• Meet and dine with other fully vaccinated individuals who voluntarily disclose their vaccination status, without masks and without distancing.
• Work in their dedicated workspace or desk without a mask.

CHOP personnel are permitted to share their vaccination status; however, they are not permitted to:

• Ask or make assumptions about another person’s vaccination status;
• Exclude anyone from a meeting/gathering because the employee chooses to wear a mask.

WORKSPACES AND DISTANCING

This increased capacity will reduce physical distancing to less than 6 feet, which is now permissible for interactions between employees carrying out work activities.

• Workspaces, touchdown spaces, and research areas will continue to be used by both vaccinated and unvaccinated staff, following masking guidelines above; Again, staff should not be asked and are not required to disclose vaccination status.
• Keep shared spaces and common areas free of clutter, paperwork, and personal belongings to allow for ease of cleaning.
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- Ensure ready access to hand sanitizer.
- Sharing of keyboards, computer mouse, and research instruments is acceptable provided staff perform standard sanitization and hand hygiene before and after use.

Please refer to https://at.chop.edu/osmo/eop/bioresponse for additional guidance.

Do I need to be test fitted 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. For more information on PPE, please see https://at.chop.edu/osmo/eop/bioresponse.

*Does being vaccinated change the percentage of people allowed on campus or the requirement to wear a mask while working on campus?

When returning to campus, keep in mind that 70% of our patients remain unvaccinated (less than 12 years of age), which necessitates that we exercise caution to protect our patients, families, and employees. Universal masking is still required in all areas accessible to patients and families.

While research buildings, including Roberts with the exception of the 4th floor subject testing space, are considered non-clinical care areas, practice universal masking whenever you are moving throughout campus — such as down a corridor, entering or leaving a building, and riding the elevator. In essence, “If you move, you mask.”

Please refer to https://at.chop.edu/osmo/eop/bioresponse for additional guidance.

*I am uncomfortable being in a large conference room with unmasked colleagues. How can this be addressed at work?

Vaccination is highly effective for both preventing COVID-19 disease as well as the ability to transmit SARS-CoV-2, the virus that causes COVID-19. Thus, it is safe for vaccinated individuals to meet in conference rooms without masks while adhering to room capacity guidelines. This level of activity is supported by the most recent guidance from the CDC and is supported by CHOP’s Bioresponse Team.

If you are not fully vaccinated, you should continue to wear masks and practice physical distancing. Fully vaccinated employees can still choose to wear masks and practice physical distancing. If you are uncomfortable at any time, speak with your manager about specific concerns and opportunities for virtual attendance.

*Are there any guidelines related to masking when employees use the Roberts gym?

At this time, there are no additional guidelines related to the Roberts gym. Please see the above question for more information on general CHOP masking guidelines.
**CHOP Research Institute FAQs for Clinical Research during the Coronavirus Pandemic**

*I’m planning a meeting in Roberts. How do I know how many staff each room can accommodate?*

All conference rooms now have QR codes that you can scan to find out capacity. Please use these when planning meetings to ensure adequate space for attendees. For additional guidance, please see: https://at.chop.edu/osmo/eop/bioreponse/Pages/New-Normal-Meeting-Room-Guidelines.aspx

**WORKPLACE CONDITIONS**

Will plans for maintaining physical distances in the Roberts Building be provided?

Signs for maintaining safe physical distances between research personnel in Roberts have been placed by Facilities.

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/bioreponse 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 the same as for patients coming in for clinical care. Research staff are responsible for confirming that 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?

Yes, the Subject Checklist needs to be completed for each subject enrolled. The checklist should be stored with the study source documentation either in EPIC or in the regulatory binder. The checklist does not need to be submitted but needs to be maintained, as the checklists may be inspected during a routine study audit. Please ensure that you are using the latest version of the Subject Checklist which can be found here.

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.

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. Masking guidance for research study subjects parallels that for clinical patients; please see the Bioresponse page for additional guidance.
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 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. Other activities need to follow local/state requirements.

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](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 on a daily basis (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 in length;
- 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;
- 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.

If you have additional questions related to monitoring visit permissibility, please reach out to ClinResearchQuestions@email.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.
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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. Screening of these participants would follow clinical screening guidelines as outlined on the Bioresponse page. Study teams also 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@email.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 (except those with aerosol generating procedures).

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

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

For MRI/Radiology scheduling, 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: https://www.research.chop.edu/center-for-human-phenomic-science

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@email.chop.edu
For research only study visits, who will pay for the required COVID-19 testing, and how much does it cost?

The research team will need to arrange COVID-19 testing per the COVID-19 testing requirements for the clinical research site (i.e. 24 hours prior to PFT). Please note that COVID-19 testing requirements may vary by clinical research core lab.

The research team will need to pay for COVID-19 testing. To ensure the charge gets routed appropriately to the research study account, study teams should add the test code to Oncore Financials as an additional procedure to the visit.

The cost for COVID-19 testing both federal and industry is listed below:

808103 COVID-19 HB INFECTIOUS DISEASE DIAGNOSTICS LABORATORY: Federal $33.79
808103 COVID-19 HB INFECTIOUS DISEASE DIAGNOSTICS LABORATORY: Industry $65.00

Please reference the "PI Protocol Checklist: Return to Clinical Research at CHOP" and the “Subject Research Checklist” as additional resources available here: https://www.research.chop.edu/announcements/faqs-for-clinical-research-during-the-coronavirus-pandemic

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

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