CHOP Research Institute FAQs for Clinical Research during the Coronavirus Pandemic

* Updates to the previous version from June 24, 2020.

GENERAL QUESTIONS

Do we need IRB approval to restart in-person visits for nonessential clinical studies?

No, additional IRB approval is not needed.

For information on making study changes, such as having in-person study visits occur by telephone or teleconference, changing visit scheduling, verbally consenting subjects, or other topics, please see the IRB FAQs: [https://irb.research.chop.edu/](https://irb.research.chop.edu/)

Which studies are able to resume research activities?

**Category I: Currently permitted**

- Essential clinical trials, SARS-CoV-2 clinical research, fully remote clinical studies

**Category II: Currently permitted**

- In-person research visit CONCURRENT with clinical visit
- Research/biobank samples may be collected, provided the in-person research visit is concurrent with clinical visit AND the laboratory team can accept the research sample

**Category III: Currently permitted for Category IIIA; Permitted June 29, 2020 for Category IIIB**

- Category IIIA: Previously scheduled in-person research visits in an affected population canceled due to COVID-19 study restrictions may be rescheduled
- Category IIIB: New in-person research visits in an affected population

**Category IV: To be decided depending on state of pandemic and safe ramp-up success through categories I, II, and III**

- Clinical research visits involving healthy adult controls as study participants

Please note that any research activities that can be conducted remotely should continue to be conducted remotely at this time.

* What counts as an “affected” population?

An “affected” population includes individuals who have, or are expected to have, the underlying exposure or disorder being studied. This would include individuals who are at risk for the diagnosis of an underlying disorder that is the subject of the research (e.g. infants being studied who are at high risk for autism). This does not include subjects considered to be “healthy controls.” Healthy control subjects will be permitted to participate in research during Category IV of the ramp-up.
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What is the current percent of staffing for research groups?

CHOP will be transitioning to 50% of research staff working non-remotely on July 6, 2020. The determination for staffing percentage is separate from the staged clinical ramp-up and will be determined by data from the pandemic.

If a study subject will have a clinical home visit, can an additional research lab/visit be conducted at that time?

Yes, if a clinically scheduled home visit is being conducted, a research visit can occur at the same time as the clinically scheduled visit in the subject’s home.

*Can research-only home visits be completed at this time?

Yes, research-only home visits in an affected population can be completed provided the following criteria are met:

- The visit can be conducted with adherence to the current non-remote staffing percentages
- Masking and hand sanitizing procedures will be followed as indicated on the CHOP Bioresponse page
- Physical distancing can be maintained during the visit
- The family is agreeable to 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

My study includes research activity at Penn. Is it approved to move forward?

Investigators who completed the CHOP-Penn REDCap survey and whose studies were categorized in Category A and Category B at Penn are approved to move forward during the first phase of Penn research ramp-up June 8. If you are unsure if your study falls into these categories, please email ClinResearchQuestions@email.chop.edu.
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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.

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.

What does it mean to bring back 50% of your research team?

Any work that can be done off-site should continue to be done off-site. Only 50% of the research workforce should be working in a non-remote setting at any one time as of July 6, 2020. Prior to July 6, 2020, only 25% of staff should be working in a non-remote setting. For example, if a research team has 4 members, at 25% staffing only 1 person should be present on any part of the CHOP enterprise or any community-based site (e.g. Philadelphia schools) at any one time; at 50% staffing, 2 people may be working in non-remote settings at any given time. Research teams can consider flexible working hours such as nights or weekends for on campus work.

Does the PI Count toward the % of staff who may be on-site?

Yes, the PI counts toward the staff total when working in a research capacity. If a PI is on site for clinical service, only then they do not count toward the % of non-remote staffing.

How does the % rule apply if I have fewer than 4 people on my team?

The goal is to have only 25% (prior to July 6) or 50% (as of July 6) of staff working on campus at any one time. Thus, if you have only 2 people on your team, each should limit their time on the CHOP campus to 25% of usual (prior to July 6) – so each person might come in on alternate half days, for example. As of July 6, for a team of 2 people, each person may alternate being on campus. PIs are responsible for organizing staff time and ensuring that they follow the % guidelines.

When will staffing increase beyond 25%?

As of July 6, staffing will increase to 50%. CHOP will be carefully monitoring the current status of the pandemic in Philadelphia, the health and safety of staff, and working with the COVID-19 Bioresponse team to determine when to allow additional increased staffing percentages.
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What if the same CRC works for multiple PIs?

The % staffing percentage applies to the PI’s research team, not the individual team member. Each PI may only have the currently approved percentage of their research team working in a non-remote setting at any given time. If a coordinator works 50% for one PI and 50% for another PI, that person may be scheduled to come on campus on separate occasions for each, but each PI will need to make sure that their team's total allocation is within the currently approved staffing percentage. If the coordinator is working on a study for the second PI, their presence on campus would not count against the first PIs staffing percentage. The PIs will need to coordinate staff time on campus.

Can we expect to make up for lost accrual?

Given personnel time and likely clinical resource limitations, studies may not be able to make up for lost accrual. PIs will need to work with sponsors and funding agencies to address accrual challenges due to the pandemic.

Will we be able to schedule patients for clinical tests to make up for lost accrual?

Given the backlog in the clinical enterprise, PIs and research coordinators will likely experience delays scheduling certain types of clinical studies. Study participants should not be scheduled unless the team can secure all necessary testing to assure patient safety and meet study endpoints.

I don't have any research subjects coming in for study visits, but I have tasks that need to be completed that I'm not able to do from home. The study sponsor wants these study tasks completed. Can I come into the office to complete them so I don't fall behind on these important study tasks?

Yes, you can come to work to perform these tasks as long as the PI maintains only the approved percentage of his/her research staff working non-remotely at any one time.

Should clinical research source documents be scanned for remote data entry?

The goal of remote work is minimize the risk of SARS-CoV-2 transmission. If a CRA is already on-site, then the data entry activities may be completed on-site in accordance with current staffing restrictions. If research source documents are scanned, then they must be handled in a secure, HIPPA compliant manner.

*What does “location critical” mean?

Location critical means that the work needs to be performed on-campus or in a non-remote setting (e.g. research in the community). Some jobs are fully location critical, and staff need to be on campus to perform all aspects of their roles (e.g. a CHOP phlebotomist), and some jobs may have a mix of location critical tasks and tasks that can be performed remotely (e.g. entering HIPAA protected data that must remain on CHOP’s campus and facilitating a research visit by phone). Tasks that can be completed remotely should continue to be completed remotely, unless coupled with location critical tasks where it would be inefficient to separate them (e.g., responding to calls from research subjects while entering HIPAA protected data that must remain on campus). PIs are encouraged to work with their study teams to decide which tasks require non-remote work and to ensure the current % staffing guidance is adhered to.
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*Is it safe to come back to work via public transit?
CHOP is working closely with SEPTA and other public transportation agencies to ensure that public transit options are as safe as possible. Additionally, CHOP physicians are serving as advisors to the Department of Public Health as they evaluate public transit safety in Philadelphia. For more information on public transit and safety during the pandemic, please see the CHOP Bioresponse page and SEPTA Reopening Guide.

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. Please contact ResearchSafety@email.chop.edu with questions about obtaining PPE.

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

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

The same conditions of work in the clinical arena should be followed in all research and clinical areas. Currently, at a minimum, universal masking is required. Please refer to https://at.chop.edu/osmo/eop/bioresponse for additional guidance.

A training module titled Return to Work – Key Safety Practices has been developed and assigned to researchers and is available in MyCareer. For questions related to this module, or to access it if unable, please contact ResearchSafety@email.chop.edu.

Do I need to be test fitted for a mask to wear in clinical areas, or can I wear the same mask that I wear in my office area? Do I need an N95 mask?

You can wear the same mask and do not need an N95 mask for routine research procedures. For more information on PPE, please see https://at.chop.edu/osmo/eop/bioresponse

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.

Current physical distancing guidelines are as follows:

1. Adjacent 6 x 6 workstations may be occupied provided that staff do not sit facing each other
2. Adjacent touchdown carrels may not be occupied.
3. 6 ft physical distancing should be maintained in all common areas
4. No more than 4 individuals per elevator in Roberts
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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 provided social distancing requirements can be maintained. The percentage limitation is on staffing, not on room use. Facilities has removed some furniture in the waiting area and provided signage to guide social distancing requirements. Researchers will need to ensure that both subjects and caretakers who accompany subjects can maintain social distancing during the research visit. 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 social 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.

My study involves visits at sites outside of CHOP Main (e.g. primary care). Can I proceed with the research at this time?

The PI will need to work with leadership from the sites where the research will be conducted to ensure that sites have the capability to accommodate research activities. Just because a study falls into a category that is able to resume does not mean that individual sites have the capability to accommodate the research at this time.

Can approved students come on site to work?

No, approved students should continue to work remotely.

How long will it take to return to normal?

It is not clear whether or when we will “return to normal.” Research teams should plan on using appropriate PPE and maintaining physical distancing for the foreseeable future.

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 our children are still home from daycare, schools or camps?

PIs are asked to be as flexible as possible and coordinate activities with their team members to try to accommodate personal challenges during this difficult time.
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RECRUITING AND SCREENING

What if my study needs to recruit healthy adult controls?

At this time, these study visits are not permitted. The timeline for allowing healthy adult controls is to be determined by the pandemic and the success of the clinical research ramp-up.

Research visits for a healthy adult recruited as part of a research subject-parent dyad/triad are allowed provided that the parental visit occurs in conjunction with the pediatric research subject visit.

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.

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.

*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 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

Before visits start, where should families wait if they arrive early for their appointment?

We encourage families to wait in their car whenever possible to support social distancing. There should be a plan for them to call the study team when they arrive, and the study team will let them know when to proceed inside for the appointment.
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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.

What monitoring visits are currently permitted at CHOP?

For information on scheduling monitoring visits, please see FAQ #17 on the IRB’s site.

Can Site Initiation Visits (SIV) occur at CHOP?

Yes, SIV may occur starting on June 29, 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.

Should I tell my research participant/parent that only one parent/guardian should accompany the subject to the research visit?

Yes, as per current CHOP guidance only one parent/guardian should attend research visits; however, there are scenarios in which both parents/guardians may attend the research visit.

Can we conduct research visits that occur at multiple sites on campus for the same study participant (e.g. The study participant has a procedure at the main hospital, another at Wood, and another at Roberts)?

Yes, provided that all in-person research visits occur on the day of the clinical encounter. Research staff and study participants and caretakers traveling between buildings should adhere to proper PPE and social distancing to maximize safety.

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

Research in the ED may begin, as long as the activities can be conducted during the course of the ED encounter. The ED’s Phase 1 ramp-up includes having clinical research staff return at 25% of typical density on June 1, and would allow research staff to interact with ED staff but not directly with patients. Staff can facilitate study enrollments using a semi-remote method where staff can ask screening questions of clinical team members and then communicate with families electronically from outside of the patient room using iPads.

Phase 2, will allow some patient/family interaction dependent on how ED Phase 1 is going as well as the trajectory of COVID-19 in Philadelphia, and would essentially match Phase 1 of the Research Institute’s plan after this.

The ED is developing further, more specific guidance that ED staff will follow. 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

When can we begin recruitment and scheduling visits for the next phase of research?

Remote recruitment for research visits can occur at any time. On-site recruitment can take place as permitted by on-site staffing guidelines.

Visit scheduling may begin if scheduling occurs remotely. On-site scheduling can take place as permitted by on-site staffing guidelines.

Please recognize that the permission to schedule a visit does not guarantee that the visit can actually be scheduled. We expect clinical research services/cores may have an extensive backlog of canceled visits and may also have limited staffing.

Although not mandated, we ask clinical investigative teams to focus on rescheduling and completing previously canceled in-person visits before scheduling new in-person visits.

Investigators are encouraged to consider the impact on study subjects/caregivers and study validity of recruitment/scheduling when there may be a substantial interval between recruitment and the actual study visit. Please ensure that recruitment language is sensitive to the current situation and consistent with CHOP messaging to families during this time. While confirming interest may be reasonable to do now, we recommend waiting to complete consent until the research visit is close at hand.

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 and radiology services that limits availability of these resources for research procedures. If your study involves radiology resources or MRI scans, please reach out to Radiology Resource Management prior to scheduling subjects.
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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 CRAAnalyst@email.chop.edu or Ronnie Kain at Kainv@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 for the CHPS PFT Core Lab). 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 “Category I/II/IIIA/B Subject In-person Visit Checklists: Return to Clinical Research at CHOP” 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.