CHOP Research Institute FAQs for Clinical Research during the Coronavirus Pandemic

GENERAL QUESTIONS

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

No, 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/

Which studies will restart first?

Nonessential, in-person studies concurrent with clinical visits (in- or outpatient) will restart first.

The second stage ramp-up of clinical studies will include in-person visits not in the context of a clinical visit. At this time, we anticipate the second stage to occur with the transition of Philadelphia into the Yellow Zone. We will provide additional guidance about the second ramp-up stage as that approaches.

Where do clinical trial visits which are equivalent to standard of care fall in the reopening phases? Since trial visits become clinical care for participants (similar to the expanded elective care CHOP is allowing now), it is unclear if they can occur in phase II or phase III.

In-person visits for essential clinical trials may take place at this time. All other in-person clinical trial visits will resume in a staged manner. As of May 26th, clinical trial visits concurrent with a clinical visit may occur. Clinical care provided outside of the context of a clinical trial is impacted by clinical research restrictions.

Where is FDA guidance available?

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.


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

Are you testing everyone for COVID19 as they return to work?
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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 25% of your research team?

Any work that can be done off-site should continue to be done off-site. Only 25% of the research workforce should be working on campus at any one time. For example, if a research team has 4 members, only 1 person should be present on any part of the CHOP enterprise or any external research site (i.e. Philadelphia schools) at any one time. Research teams can consider flexible working hours such as nights or weekends for on campus work.

Does the PI Count toward the 25% of staff who may be on-site?

Yes, the PI counts toward the staff total.

How does the 25% rule apply if I have less than 4 people on my team?

The goal is to have only 25% 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 – so each person might come in on alternate half days, for example. PIs are responsible for organizing staff time and ensuring that they follow the 25% guidelines.

When will staffing increase beyond 25%?

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 increased staffing percentages.

What if the same CRC works for multiple PIs?

The 25% staffing percentage applies to the PI’s research team, not the individual team member. Each PI may only have 25% staff on site 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 study (and total more than 25% individual effort), but each PI will need to make sure that their team’s total allocation is only 25%. If the coordinator is working on a study for the second PI, their presence on campus would not count against the first PIs 25%. 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. In short, do not start what you cannot finish.

I don't have any research subjects coming in for study visits, but I have data entry and remote monitor visits 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 25% of his/her research staff working on campus at any one time.

ACCESS TO PPE / RESEARCH SAFETY

How do we obtain PPE for clinical research personnel?

Research Safety initially will supply PPE for both wet lab and clinical research. At this time, do not order PPE independently from COUPA. In the near future, each research group will need to purchase appropriate PPE for its workforce. PPE should not be taken from clinical teams or arenas. Please contact ResearchSafety@email.chop.edu with questions about obtaining PPE.

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.

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 care or conduct. For more information on PPE, please see https://at.chop.edu/osmo/eop/bioresponse

WORKPLACE CONDITIONS

Will plans for maintaining physical distances in different settings be provided?
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Resources for maintaining safe physical distances between research personnel in Roberts and dry-lab portions of other buildings are being developed and will be provided before activities resume.

Can students come on site to work?

No, 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.

RECRUITING AND SCREENING

What if my study needs to recruit normal controls?

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

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. During the first phase of clinical research ramp-up, only research visits concurrent with a clinical visit will be permitted. Screening for the clinical visit will be performed by clinical staff and will be used as the screening procedure for the research visit.

STUDY VISIT RELATED QUESTIONS

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 attend research visits; however, there are scenarios in which both parents/guardians may attend the research visit.

What about research visits that happen immediately before or after a clinical visit via telehealth? Are we able to start those?

Only if the research visit can also be conducted remotely. Study participants are not permitted at this time to come to CHOP only for a research encounter. During the first phase of the ramp-up (starting May 26th), only study participants who are on campus for a clinical visit may participate in research that coincides with the clinical 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.

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

Research in the ED may begin on May 26th, as long as the activities can be conducted during the course of the ED encounter. The ED is developing further, more specific guidance that ED staff will follow.

Can research visits still occur in the Roberts Building?

Research visits can take place in the Roberts building provided that the visit is concurrent with a clinical visit on the CHOP Main campus.

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

OTHER QUESTIONS

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.