Research Questions related to Clinical Trials and Non-interventional Clinical Research:

**Background:**

At this time, all on campus research activities are paused except for the following:

1. Essential clinical trials
2. Safety visits that cannot be performed remotely on nonessential clinical trials

For purposes of this guidance, essential clinical trials are “Those that enroll or follow patients with life-threatening or serious conditions for which clinical research holds out the prospect of direct benefit. Patients with life-threatening or serious conditions who are undergoing critical safety testing follow-up are included in this definition.”

**General Questions:**

**How long will this pause remain in place?**

The current pause will remain in place until further notice. The precise duration of the pause depends on the progression of COVID-19.

**Who determines whether a clinical trial is essential?**

The Principal Investigator (PI) should make the initial determination that a clinical trial is essential. If the PI believes the trial is essential and there may be study visits that cannot be conducted remotely they will need to follow the process discussed in the “What study visits may continue?” FAQ below.

Recognizing that this determination may be complex, the CRSO Leadership Team is available to discuss this determination with Principal Investigators. Please contact Dr. Richard Aplenc, Dr. Jeffrey Gerber or Dr. Betsy Goldmuntz for any questions or assistance.

**What study visits may continue?**

In-person contact with either study subjects or biospecimens may continue only in the three following scenarios:

1. Essential clinical trials
2. Safety visits that cannot be performed remotely on nonessential clinical trials

The IRB and Research Institute have developed a process to review these three clinical research scenarios. This additional review is required to ensure that the risks to study subjects and research personnel are minimized during the COVID-19 pandemic and that appropriate resources are available to support the proposed clinical research.
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In brief, a reportable event (a prospective protocol deviation) will need to be submitted in eIRB for every study in the three scenarios listed above. Submitting this reportable event via eIRB will ensure consistency between determinations, provide a complete regulatory record for the study, and increase transparency for investigators and research study staff. Guidance for this reportable event submission is available on the IRB website at https://irb.research.chop.edu.

With each reportable event, the investigator will need to complete and submit an Essential Clinical Research Survey in REDCap. A link to this survey will be sent to each Principal Investigator. This survey is designed to provide the IRB and the Research Institute with the information necessary to confirm the designation of essential clinical trial status and determine whether in-person contact with either study subjects or biospecimens is approvable. We have sought to balance the information required for this decision with administrative burdens on investigators and staff.

Additional information on this process can be found here: https://at.chop.edu/research/blog/Lists/Posts/Post.aspx?ID=83

In-person visits for non-essential visits need to be rescheduled for a later date or conducted by telephone or teleconference.

What research study staff should work remotely?

Until further notice, all research study staff are required to work remotely unless their presence is required for the safe conduct of an essential clinical research study or safety visit.

Will the services of the Investigational Drug Service (IDS) be available?

Yes, the IDS will continue to dispense study drugs as usual and hours of operation will remain the same. However, per CHOP guidelines, IDS is not allowing study teams to schedule site visits involving an external monitor or representative until 5/4 at the earliest. Previously scheduled visits through 5/1/20 have been canceled.

Please see IRB FAQs for additional guidance regarding IDS: https://irb.research.chop.edu/

Where is IRB guidance available?

For additional 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/

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.
Is research related to COVID-19 exempt from the clinical research pause?

Research related to COVID-19 that requires direct patient contact is in principle exempt from this pause. Please contact Dr. Richard Aplenc, Dr. Audrey John, Dr. Brian Fisher or Dr. Jeffrey Gerber to discuss COVID-19 research protocols that may be exempt from this pause guidance.

Questions Regarding Specific Scenarios:

Can in-person study visits on essential clinical trials be delayed?

An in-person study visit on an essential clinical trial may be delayed to decrease the risk of COVID-19 to the study subject or research study staff. If a visit is delayed, the sponsor of the study must be notified. If a research participant requires medical attention, the investigator needs to ensure that the appropriate referrals are made to protect subjects. The visit delay should be reported to the IRB as a prospective protocol deviation (if possible) or promptly after they occur. Reporting to the FDA will be the sponsor’s decision. The IND/IDE Office can assist CHOP sponsor-investigators with FDA reporting questions.

Can study visits occur by telephone or teleconference?

Study visits may occur by telephone or teleconference. Please see the IRB FAQs for additional guidance:

https://irb.research.chop.edu/

Can a non-essential clinical trial that utilizes only virtual visits continue?

Yes, a non-essential clinical trial using only virtual visits may continue provided that study staff can appropriately conduct the study while working remotely.

Is there suggested language for a protocol deviation for patient safety related to COVID-19?

Please see the IRB FAQs for guidance on reporting protocol deviations:

https://irb.research.chop.edu/

My essential clinical trial remains open but has sample collection that does not benefit the patient and is not related to patient safety. Should these samples be collected?

Sample collection should not occur.
My essential clinical trial remains open but has survey data collection that does not benefit the patient and is not related to patient safety. Should these data be collected?

Survey completion may occur if performed remotely. Survey completion should not occur if either the study subject or research staff would need to travel to CHOP for survey completion.

Can my biobanking study continue during the pause?

The biobanking study may not continue during the pause.

My observational study takes place in the community setting. May it continue?

The study may continue only if all study procedures can be performed remotely AND community leadership allows the observational study to continue using only remote study procedures.

My interventional study takes place in the community setting. May it continue?

Essential clinical trials in the community setting can continue if community leadership allows the study to continue.

Non-essential clinical trials may continue only if all study procedures can be performed remotely AND community leadership allows the observational study to continue using only remote study procedures.

Should screening visits for new study subjects be rescheduled/postponed?

Screening visits for essential clinical trials may continue.

Screening visits for non-essential clinical trials may continue if the screening visit and all upcoming study activity can be performed remotely or delayed until after the pause is lifted.

Should research staff travel to work to administer a survey or test to patients on non-essential clinical trials?

Research study staff should not travel to CHOP to administer a survey or a test to a study subject on a non-essential clinical trial unless there is an important safety consideration for the study subject.

Can research visits still occur in the Roberts Building?

No. The Roberts building will only be open to CHOP personnel with IDs. Non-CHOP personnel cannot come to the Roberts building.

We have research subjects who need to return unused study drug or study supplies back to the site. Can subjects ship these supplies back to CHOP?

When feasible, please wait to collect any unused study drug or supplies until the time of the next onsite visit. If there is time sensitivity for returning supplies (e.g., a study device containing safety data to be
read), send prepaid shipping materials to subjects. ORC@email.chop.edu can advise on questions related to shipment of study supplies back to CHOP.

How do we document protocol deviations in EPIC?

COG and NCI have acknowledged that protocol deviations may be necessary during the COVID-19 pandemic. If a deviation is necessary because of, for example, travel restrictions or Research Institute limitations on clinical research activities, please document the deviation in the patients record.

With Charles Phillips’ help, we have created a dot phrase in Epic to document protocol deviations:

.COVID19ProtocolDeviation

Documentation of Covid-19 Related Protocol Deviation
Protocol number: ***
Description of protocol deviation: ***
Rationale for deviation: ***
This deviation was related to circumstances surrounding the COVID-19 pandemic.

The description of the deviation and the rationale can be brief.

If you think the protocol deviation impacts patient safety, compromises the overall integrity of the study data, or affects the patient’s willingness to continue their participation in the study, then please send an email to datarequest@email.chop.edu. These deviations require expedited reporting to the IRB.

Research Recruitment

Should research recruitment efforts be paused?

The following recruitment efforts for non-essential clinical trials may continue:

1. A potential subject contacts the study team to inquire about a study
2. A clinician investigator discusses a potential study with a patient when the clinician is already seeing in a clinical visit necessary for clinical care
3. The investigator has a pre-existing relationship with the subject and recruitment is being done individually
4. Email blasts and online posts for studies that can be conducted completed remotely may occur provided that the recruitment language is re-evaluated to ensure consistency with CHOP messaging and sensitivity to patient and family experiences during the COVID-19 pandemic

All recruitment efforts should take place only if all clinical trial visits will be completed remotely and no parts of the study involve violating current social distancing mandates (e.g. does not require subjects to conduct in-person activities with any individuals whom they would not otherwise interact).
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Non-essential studies that involve in-person visits, even if the investigator’s intention is to schedule those visits after the social distancing requirement is lifted, need to continue to pause recruitment at this time as it is currently unknown when research visits may resume. This will be continuously evaluated and the FAQs will be updated as soon as it is permissible to begin recruitment for those studies again.

The REC is available to provide recruitment language review and guidance during this time. The REC is also serving to collate information on subject feedback, so please direct any recruitment opt-out requests or recruitment concerns during this period to the REC. For more information please contact participantrecruitme@email.chop.edu.

As always, only IRB approved recruitment methods and language may be used.

**Financial/Personnel Questions**

Who is responsible for financial costs for clinical research protocols during the pause?

Principal investigators remain responsible for clinical research costs during the pause and are encouraged to manage research costs carefully in conjunction with their Research Business Manager.

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](https://grants.nih.gov/grants/natural_disasters/corona-virus.htm)

What will occur if there is not enough work for research assistants/coordinators on Alternative Work Arrangements due to low visit volume?

Only the minimal staff required to perform essential in-person visits should be present on the CHOP campus. Otherwise, to promote social distancing, all others should remain at home until further notice even in the absence of tasks that can be performed remotely. A work schedule for each team should be developed to share the burden of coming to CHOP to support essential clinical trials.

Will research study staff be required to use PPL?

Research study staff working at home will not be required to use their PPL with the expectation that there will be other non-study subject related work to perform during this temporary pause.

For employees who have available bandwidth, please talk with your manager and also see CHOP’s talent marketplace to be matched with work during this time: [https://chop-covid-19-help.sharetribe.com/](https://chop-covid-19-help.sharetribe.com/)

For questions related to Salary Support during the COVID19 Pandemic, please see the April 3rd CSO Connection available here: [https://at.chop.edu/research/blog/default.aspx](https://at.chop.edu/research/blog/default.aspx)
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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

OnCore Support Office:

Is the OnCore Team working remotely?
The OnCore team is working remotely.

How do I contact the OnCore team?
Please email OnCore@email.chop.edu, which is monitored consistently by the OnCore team. A team member will respond to your inquiry and set up a virtual meeting as needed.

I am having difficulty contacting the OnCore team, what should I do?
OnCore receives a large volume of email, so please allow 1-2 business days for a response. If urgent, or you have not received a response after 2 business days, please contact Kristina Harr.

REDCap:

Is the REDCap Team working remotely?
The REDCap team is working remotely.

How do I contact the REDCap team?
Please email REDCap@email.chop.edu, which is monitored consistently by the REDCap team. A team member will respond to your inquiry and set up a virtual meeting as needed.

I am having difficulty contacting the REDCap team, what should I do?
REDCap receives a large volume of email, so please allow 1-2 business days for a response. If urgent, or you have not received a response after 2 business days, please contact Lara Lechtenberg.

IND/IDE Support Office:

Is the IND/IDE Team working remotely?
The IND/IDE team is working remotely.
How do I contact the IND/IDE team?

Please email INDIDE@email.chop.edu, which is monitored consistently by the IND/IDE team. A team member will respond to your inquiry and set up a virtual meeting as needed.

I am having difficulty contacting the IND/IDE team, what should I do?

The IND/IDE email box receives a large volume of email, but we regularly respond within 1 business day. Given the current climate, we will also be periodically checking this email box outside of regular business hours, including evenings and weekends. If you have an urgent issue or have not received a response, please contact Heather Cathrall.

What if I need to put together a submission packet for the FDA?

The IND/IDE Office is currently supporting electronic FDA submissions. Paper submissions can follow at a later point in time and the IND/IDE office is helping to coordinate and track this. Please contact the IND/IDE office for guidance on FDA submissions during this time.

Please note that annual reports and other submissions still need to be submitted to the FDA.

FDA reporting for IND/IDE Holders:

The IND/IDE Office will work with IND and IDE holders at CHOP to determine the best approach for notifying the FDA of deviations in visit schedules or procedures during this time. We can provide guidance on whether the deviations should be reported with an informational amendment or with the annual report based on the deviations that occur.

What assistance is available for a COVID-19 Treatment IND?

If you need to treat a COVID-19 patient with an investigational drug, please contact Greg Podsakoff from the IND office and Dr. Katie Chiotos or Dr. Brian Fisher directly in addition to the IND/IDE email box. You may also contact Dr. Richard Aplenc or Dr. Jeffrey Gerber. We have already been supporting the Division of Infectious Diseases and providing guidance in this area and are available to support you outside of regular business hours.

Recruitment Enhancement Core (REC):

Is the REC Team working remotely?

The REC team is working remotely.

How do I contact the REC team?

Please email Participantrecruitme@email.chop.edu, which is monitored consistently by the REC team. A member of the team will respond to your inquiry and set up a virtual meeting with you as needed.
Will study recruitment be paused given the social distancing guidance?

Recruitment for non-essential clinical trials that involve in-person visits (including specimen handling) or require participants to break current social distancing mandates are being paused at this time. Recruitment for essential trials and studies which can be conducted completely remotely are being supported by the REC. The REC is available to work with investigators to develop recruitment strategies, provide language review, and assist with recruitment material development. Please contact the REC or email Heather Cathraill for any questions on recruitment.

Clinical Trials Financial Management (CTFM):

Is the CTFM Team working remotely?

The CTFM team is working remotely. However, a staff member will be onsite at Colket and available to maintain the PRC subject compensation and reimbursement card distribution activities.

How do I contact the CTFM team?

Please email your contacts directly. CTFM teams also consistently monitor email inboxes of each of our three units: Budgeting, Research Registration/Charge Review and Accounting. A team member will respond to all inquiries and set up a virtual meeting with you if needed. CTFM team members will also check their voice mail three times per day.

- Budgeting: CRAanalysts@email.chop.edu
- Research Registration and Charge Review: CTFM@email.chop.edu
- Accounting: CTFMACCT@email.chop.edu
- PRC program: PRC@email.chop.edu

I am having difficulty contacting the CTFM team, what should I do?

If you have an urgent issue or have not received a response to an email or voice message after one business day, please contact CTFM Director Ronnie Kain or call 267-505-5420.