Questions for Town Hall in Preparation for Phased Reintroduction of Clinical Research

Question	Answer
What types of amendments/protocol changes in regards to reactivation need to be submitted to the IRB for approval?	No longer under Emergency status, so all require IRB approval. Transitioning face-to-face visits to remote, consider semi-permanent for foreseeable future Obtaining consent electronically Changes to make study feasible in current environment
What is the current PPE availability for RCs going into inpatient rooms (PICU and 6th-9th floor) with droplet precautions (non-COVID)? Where can we find PPE on each floor? Where is the the most-up-to date information of when to wear a mask or no --(i.e. a back in March I was told not to use a mask if I wasn't going close to the patient)?	When you enter CHCO, you will be asked if you're working in a clinical area; if yes, you will be given a surgical mask and a brown paper bag to store it If face shield is needed, each clinical area has a PPE coordinator / storage location; coordinate directly; please always reference COVID-19 policy and PPE guidance as this changes over time
Could you please clarify the mandates regarding COVID screening for research participants? Will all participants, regardless of type or duration of study visit be required to obtain a COVID swab test prior to a research visit? Will this only apply to patients who are having inpatient research visits? I've heard that PIs will be responsible for paying for the cost of the swab test -- will this be billed in EPIC?	COVID-19 policy specify who/when is required Inpatient procedure or admission, COVID testing will happen with 24 hours in advance or at mobile clinic Ambulatory participants aren't required to have test prior to visit at this time Studies themselves will be charged $51/federal study, $225 industry study for each test, will impact budgets (Erin confirmed)
Is there/will there be a limit to the number or type of family members permitted to attend outpatient clinic visits with a research participant? (Typically there may be multiple siblings and/or other family members accompanying the patient due to lack of child care, etc.) Is it suggested or required to advise parents/guardians to bring as few family members as possible?	Currently allowing 2 visitors over the age of 18 No siblings under the age of 18 allowed in clinics Any siblings who show up will be asked to go to creative play center or reschedule Visitor restrictions can change, which is why it's important to continue to check COVID policy
Is there an approval process/protocol for the presence non-clinical research personnel in the Hospital for the purpose of preparing for human subject visits? For example, programming imaging protocols for a visit deemed 'essential'?	There is no formal approval process for non-clinical research staff. We ask that all non-clinical staff try to work remotely if at all possible with the understanding that on-site access might be needed to perform job functions. Please follow all CHCO guidelines for screening and masking requirements.
What are the plans for social distancing in the CTRC on hallways E and D?	Limiting volume of team members in clinic, consistent with CHCO guidance and aligned with all ambulatory clinics to keep volumes at 50% capacity Approved for 20 participants daily, therefore limited to 20 coordinators/day (maximum) + CTRC nursing staff. See CTRC 3rd floor space plan for full details. All CTRC users received this as an attachement on 5/18, it will be available on the CCTSI soon.
How do PIs obtain PPE, cleaning supplies, etc. for research visits and study personnel that do not occur in the CTRC? We have components of our research visits that occur at CHCO and others that occur in Ed2South.	Coordinate directly with individual leadership where visits are occuring AMC buildings (ex: ED2) require space plans, which must be approved through AMC to operationalize Submitted space plans must include volume of PPE required and who is supplying PPE; if you don't have sufficient PPE, then request through plan/application and will be reviewed and approved
What are the plans for overnight/inpatient research visits?	Please refer to campus guidance document, If CTRC services are needed, Groups 1 and 2 are being accepted at this time. All other requests can be submitted be the guidaance and will be evaluated based upon the ability for the clinical
What should study teams do now to prepare for reactivation? (e.g. COVID Skillsoft module, amend protocols/consents etc. to accommodate remote visits, add recommended participant screening language)	Take required Cornerstone module (assigned in your email inbox) Adapt protocols as necessary Review EPI-Alerts or Reactivating Clinical Research page on CHRE SharePoint as source of truth before every shift Touch base with your supervisor before initial return to campus
If a participant in a non-essential research protocol is already coming in to the clinic for a clinical visit and we can minimize the staff coming in to do that visit, will you give it consideration even though is non-essential?	This is study-dependent. We are proritizing visits based on the AMC campus-wide prioritization framework, distributed from the VC for Research Research on 5/15. This framework includes protocols that have participants coming in for SOC visits. Only studies on the phase that we are reviewing will be considered for CTRC. For other areas, check with the medical director of that unit.
What if they are coming in for a clinical reason, and they are on a study we can collect samples for?	This is study-dependent. We are proritizing visits based on the AMC campus-wide prioritization framework, distributed from the VC for Research Research on 5/15. This framework includes protocols that have participants coming in for SOC visits. Only studies on the phase that we are reviewing will be considered for CTRC. For other areas, check with the medical director of that unit.
What are the definition for Group 1 vs. group 2 research studies?	Please refer to campus guidance document
A single protocol could fit into two potential groups, for example some participants already enrolled and progressing while another step may be permission to enroll new participants.	Review and approval will be granted separately for these activities. Reviewers can approve either for "Completion of currently enrolled participants only" OR for ""Completion of currently enrolled participants and enrollment of new particpants". Please refer to campus guidance document to assess a prioritization group for your overall protocol
Where will these slides be posted, so research teams can access the links to website pages?	Reactivating Clinical Research page on the CHRE Website
Are submissions to the reactivation portal required for all studies, or only for studies where a research team member will be interacting with a patient in-person? For example, if the research visit is going to be completed by a clinic staff member who is already back in clinic, is a submission to the reactivation portal	All clinical research protocols requiring on site visits or biospecimens are being asked to be submitted. Please follow the submission guidance to submit protocols.
Are coordinators allowed to go into the processing rooms to pick up their processed samples on days where patients will not be in the CTRC? For example, on Fridays?	CTRC Nursing will staff the D Hallway Processing Room (B3542) during our business hours. If you need to collect your samples during your off hours, then yes, you can go in and access your samples. Only one person can be in the processing room at a time.

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Previously, we were informed by RI that if changes in protocol is only to be done during this time of COVID, there is no need to submit an amendment. Are you saying that this is no longer true? That means all changes we are making in the protocol need to be submitted as an amendment. Just wanted to confirm I am on the same page	No longer under Emergency status, so all require IRB approval. Transitioning face-to-face visits to remote, consider semi-permanent for foreseeable future Obtaining consent electronically Changes to make study feasible in current environment
To be clear, will the COVID-19 testing charge apply to all in person patient visits?	COVID-19 policy specify who/when is required Inpatient procedure or admission, COVID testing will happen with 24 hours in advance or at mobile clinic Ambulatory participants aren't required to have test prior to visit at this time Studies themselves will be charged $51/federal study, $225 industry study for each test, will impact budgets (Erin confirmed)
Another question: If my study is limited to surveys, do I need to go through the reactivation process? Some of my studies can do surveys either via mail in or telephone participation and I don't see why I should have to go through the reactivation process.	All clinical research protocols requiring on site visits or biospecimens are being asked to be submitted. Please follow the submission guidance to submit protocols.
For visits in which mothers and babies are both participating (I'm planning to perform the protocol from behind a glass window), is there an exception to the 18+ policy?	If the mother and baby are both participants, they should both have an encounter in EPIC and would both be patients. They would be able to have one other adult at the visit >18 years of age. No siblings are allowed. If a sibling is brought in to a visit, there may be room in the Creative Play Center (if it has enough staff), or the family could be asked to reschedule their appointment. If you are only collecting surveys, do these participants need to come into the institution, or can you conduct this visit remotely? If you are conducting this visit in an exam/clinic room you would need to wear a face shield.
Also, if COVID testing becomes required for ambulatory visits, is there consideration of the cost for small 501 (3c) funded pilot studies? Would we get the federal rate for those studies (I'm talking about an award that is $7,500-$15,000).	We will address this if guidance changes, For now ambulatory visits are not requiring COVID-19 testing.
If you move your protocols to 100% Telehealth (i.e., no need to leave their house) do we have to submit through the new portal? Or can we just submit the amendment and start w/IRB approval?	All clinical research protocols requiring on site visits or biospecimens are being asked to be submitted. Please follow the submission guidance to submit protocols.
Is there any updated guidance regarding on-site monitoring visits for industry studies?	We will update as we know more. No monitoring on-site will be allowed at this time.
Lisa mentioned we now need to schedule more complex proessing time in one of the appicable processing rooms using the schedulign pool. Is there a template to use when sending a request fro this, if it is simply indicating the day and time necessary>	CTRC Nursing will staff the D Hallway Processing Room (B3542) During our Business Hours. You can schedule the additonal processing rooms as a Resource with Research Scheduling - Provide Scheduling the details for the length of time you need Room B3482 (Ambulatory Back Hallway Processing Room) - One centrifuge - Room A4330 (NICU Processing Room), 2 centrifuges - Room A9481 (9th Floor Processing Room) one centrifuge.
If our research visit coincides wirh a clinic visit can we enroll/recruit patients during this time?	You can only enrol new partcipants when you have approval to do so, even if they are already here for a clincial visit. This is study-dependent. We are proritizing visits based on the AMC campus-wide prioritization framework, distributed from the VC for Research Research on 5/15. This framework includes protocols that have participants coming in for SOC visits. Only studies on the phase that we are reviewing will be considered for CTRC. For other areas, check with the medical director of that unit.
I have a study in which participants mail in samples that need to be processed by CHCO lab and thus need and epic encounter. Even though I am doing the visit remotely, what kind of apprval so I need in order to have an EPIC encounter created so that I can process labs and send down to CHCO lab	This would fall under Group 2 in the priorotization framework: 2.e Complete visits for enrolled participants to therapeutic or non-therapeutic protocols that require on campus processing but no participant contact (includes large data set analysis, processing of specimens). We are currently accepting Group 2 applications
If a protocol has been approved on the essential visit portal. If all visits are conducted ar CHCO does the study need to be submitted to the portal	Those protocols that have already received approval, whose entire protocol occurs within CHCO only, do not need to reapply. They are approved as Group 1. However, if any part of a previously approved protocol occurs outside of CHCO, it is necessary to reapply to ensure that all sites are available to conduct study visits and/or accept biological samples.
How long would you expect approval to take once you submit a protocol for phase q1 or 2. Is ther anywhere to check status if PI's are asking?	This is dependent the protocol. For those that need AMC plus CHCO review, this process could take 1-2weeks. Our goal is to review CHCO only protocols within 72 hours.
Are the 20 visits in the CTRC space including BI, RI and CHIP and anyone using that space?	Yes, this includes all teams using the space in Hallways D&E and the Wellness Center
What if your protocol contains elements at Leprino or BDC or contains elements of higher intensity or risk. Can you temporarily omit these procedures from your protocol and proceed with the approvable parts? And if so is a COMIRB amendment required to omit some procedures or can they be documented as a protocol deviation due to COVID?	The IRB emergency COVID status is no longer in effect so all modifications require an amendment. You can modify your protocol as you see fit, based on the science.
Are there venues for those research assistants doing clinical chart work as opposed to patient contact related Whar are the opportunities for access to the OR for gathering research data?	Please follow the submission guidance to submit this protocol for approval and then, if approved, work with OR-specific leadership to determine feasblity approval.
What protocol change must be submitted to the HSR amendment portal?	Any changes that result in calendar or financial changes in OnCore
Couple of caveats about telehealth; telehealth visits are limited to in-state patients and getting labs is often difficult, current radiology procedures need to be prescheduled . Is it correct to expect that studies requiring studies under anesthesia should be deferred for now?	That is protocol-dependent. Please follow the submission guidance to submit this protocol for approval and then if approved work with resource specific leadership to determine feasblity approval.
Is there any prediction regarding when group 3+ will be able to reactivate?	Not yet. This will be dependent on Phase 2 reintroduction. Currently, you can apply for approval for protocols requiring CTRC services for groups 1 and 2. For all other CHCO protocols you can apply for groups 1-5 at this time. However, there is no specific timing for the starting group 3 visits.

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Can you please go over the different research groups please? If the study needs to be approved to continue the study can you please walk a little more on how this looks application submission and approval looks like please? Is it just specific studies that can be submitted right now (interventional etc)?	Please refer to the campus guidance document for complete definition of the phases and to the CHRE website (Link) for detailed information on when and how to apply
Is the PPE for the visit not automatically provided by the facility?	For CHCO, you will be provided with PPE, as needed. Please refer CHCO policies to obtain the correct PPE
Is there a timeline for phase 3	Not yet. For protocols requiring CTRC services groups 1 and 2 are being accepted for submission at this time. For all other CHCO protocols you can submit groups 1-5 at this time. Please refer to the guidance document for feasbility review and approval
Can be submit requests for phase 3 visit but will not need CTRC services. Example being seen for clinical care at CHCO	Yes for non-CTRC protocols we are accepting group 3 protocols for review at this time
You mentioned limiting coordinators but what about nurses, np, sub i or PI	Any non-provider, non-CTRC staff member will be part of the 20 team members per 20 participants per day. Providers (NP's, physicians) are not inlcuded in these 20 team member's. We recognized our Providers have other clinical responsibilities that are bringing them into CHCO each day. They are not inluded in the 20 team member limit.
Can we use our own nurses? What if budget or cost is an issue?	Yes, of course you can use your own nurse. However, this is still part of the 20 team members per 20 participants per day. If a nurse is required at the study visits, can that nurse also perform the coordinator duties that day, for eaxmple? It might be necessary ro combine roles until restrictions are eased. You will need to limit the number of personnel and partner with CTRC nursing when you can. We understand that cost is an issue for everyone, including the CTRC, but, once our daily limits are reached, we will need to stop scheduling for that day so please consdier the cost-benefit ratio for your study and other studies using this space. We will be monitoring the number of study staff per visit to insure that all approved studies have access to CTRC space and resources as we ramp up.
Can we tag on a clinical visit without portal approval since we are not using CTRC services?	No, all clinical research visits requiring on site visits or biospecimen managment should be submitted. Please follow the submission guidance to submit protocols.
How are university employee researchers (CHCO affiliates) getting approval to be in the hospital? For example in the case of protcoling for approved radiology studies; we dont need to contact patients, but staff need to come in to the hospital to prepscanners and possibility assist with exam (no patient contact). How to get approval for their presence? University or hospital? Seems university needs to invite employees back on campus? What aout CHCO?	There is no formal approval process to return on-site to CHCO. Please complete all required training (Skillsoft or Cornerstone) and follow the guidelines for screening and masking for CHCO.
Will there be any consideration of visit windows when deciding which 20 participants will be scheduled on a given day?	We will need to assess this on a case by case basis, but be aware of these constraints as you get close to visit window timelines
If a study is amended and IRB approved to require no patient contact (for example, e-consent and red cap surveys) does it need to be submitted for reactivation before initiating?	All clinical research visits requiring on site visits or biospecimen managment should be submitted. Yes, please follow the reactivation process as referenced in the campus guidance document
For research happening in the ED , most studies dont fit groups 1 or 2 but have minimal if no patient contact. Is it possible that these could get reviewed quicker	If there is truly no patient contact, they would not need to be reviewed. Please follow the submission guidance for minimal contact protocols and, if approved, work with ED leadership to determine feasbility approval for studies .
Is it considered telehealth visit if doing it by phone?	If done by phone, the visit is not considered telehealth. Plese follow the standard documentation guidance for research phone encounters.
for protocols that are currently still active that have been having essential visits, do we need to submit the new redcap survey for reactivation	Those protocols that have already received approval, whose entire protocol occurs within CHCO only, do not need to reapply. They are approved as Group 1. However, if any part of a previously approved protocol occurs outside of CHCO, it is necessary to reapply to ensure that all sites are available to conduct study visits and/or accept biological samples.
Is there any additional guidance for telehealth visits out of state?	Please reference research telehealth guidance document https://childrenscolorado.sharepoint.com/:w:/r/sites/affiliate/CHRE/_layouts/15/Doc.aspx?sourcedoc=%7B57F7DE9C-08F1-40A3-9554-C706277DA0E4%7D&file=Research%20Telehealth%20Communication_April%208%202020.docx&action=default&mobileredirect=true&cid=60fc338e-7707-4b79-8489-254fb1f9a9a7&wdLOR=c67AB9D8A-AA3B-C84C-B5F1-0201F8D6C6B9
We had issues where our patients could not acces Vidyo because they were"outside" of their scheduled time. Someone from MYchart said that we may be able to use Bidyo outside of EPIC. Is this possible and if so, how couls we go about doing this?	Answers pending communication with our telehealth partners
What is the reactivation plan for Monitoring visits and other in person visits. Can we be provided a tentative timeline for reactivation or have an approval process? A document we (as employees) can share with our PIs and even the Sponsors so everyone has an idea of what is happening locally would be very beneficial.	We will update as we know more. No monitoring on-site will be allowed at this time.
What resources are available to guide our next steps?	We will continue to keep the research community up to date with further guidance as it becomes available. Please refer to the CHRE website and sharepoint, along with the campus guidance for support on next steps.