

Town Hall: Planning for a phased return to clinical research activities



UNIVERSITY OF
CALGARY



Alberta Health
Services

****This session will be recorded****

****Please turn off your microphone & video****

****Use the chat box to post questions for the Q&A period****

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Objectives

- Share information about how/when clinical studies may begin to resume at UC and in AHS facilities
- Gather your feedback about where you need more information or support to reopen safely
- Provide an opportunity to ask questions, recognizing that we will not have all the answers

Current environment

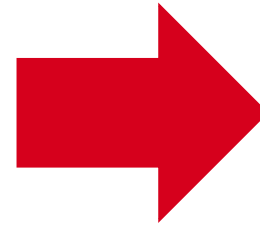
- Most faculty, staff, postdocs, and students are working from home
- At UC, only “Critical Research” is proceeding and HMRC is the key site
 - interventional studies where participation offers therapeutic benefit
- At AHS, many clinical sites are phasing back into full operations and their capacity to support research is dependent on how severely they were impacted by the pandemic
- Province of Alberta is proceeding with their relaunch strategy (May 25)

Current environment

- UC is planning a phased return to campus
- Rules at UC are set by the Government of Alberta, and implemented by UC Leadership – CSM follows the lead of the UC Executive Leadership Team
- At AHS, the Health Evidence & Innovation department (led by Marc Leduc) is working with the clinical sites to organize and communicate AHS guidance for researchers

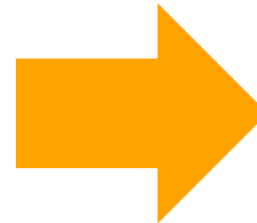
At UC: a new type of research designation has been created

- Research related to the COVID-19 pandemic
- Clinical research where participant health may be at risk
- Cases where significant data would be lost
- Contract work in which deliverables must be met



Critical Research Designation

- Grad students or postdocs who must complete work to advance their program or appointment
- Time-sensitive on-campus activities
- Time-sensitive field or community data collection



Expanded Research Designation

****Not applicable to Clinical Research as of May 25, 2020**

What is “Clinical Research”?

- "Clinical research has the goal of improving the diagnosis, prevention and treatment of disease and injury, and improving and evaluating the health and quality of life of individuals....Clinical research includes living human participants, human tissues, human remains, cadavers, biological fluids, embryos, fetuses and patient information. Excluded from this definition are in vitro studies that utilize human tissues that cannot be linked to a living individual.” (see acrc.albertainnovates.ca)
- CIHR pillars 3, 4 and much of 2
- Today we will focus on **Research involving human participants**

Clinical research at UC

- non-critical studies involving human participants will not yet resume in UC facilities
- UC non-critical studies involving human participants will not yet resume in the community or in the field
- Critical studies will continue and those that were previously suspended may resume if/when feasible
 - in the HMRC
 - (in AHS facilities)
- Resumption of non-critical clinical studies at UC will depend on multiple factors:
 - lessons learned during phase 1 (laboratory studies)
 - directives from GoA, City of Calgary, ELT, CMT
 - the course of the pandemic

Core philosophy: now and in the immediate future

- Maintaining the safety of study participants, staff and trainees is paramount
- No PI is required to reopen their research program
- PIs may not compel their staff and trainees to come to work
- Only work that cannot be completed at home can be conducted on site
- Physical distancing will mean that work proceeds more slowly than usual
- The process will evolve over time

Worst case scenarios

- UC and AHS policies must help us to avoid bad outcomes:
 - a researcher is found to have pressured a student, postdoc, staff member to return who was uncomfortable doing so
 - a researcher or unit is found to be violating government directives for safe operation
 - a significant COVID-19 outbreak is found to originate in a research setting, or we lose someone to COVID-19
 - a UC field researcher brings COVID-19 to an isolated community

Regulatory considerations

Remember to:

- Report all protocol deviations caused by the pandemic to the REB and the study sponsor
- Document any process adjustments due to the pandemic (e.g. virtual visits, sponsor mail-out of study meds to patients, electronic signatures)
- Consult with the REB about the need for re-consenting
- Follow acceptable remote monitoring processes:
 1. Sending redacted copies of source data to sponsors
 2. Screen sharing through the UofC license of Microsoft Teams platform

General Principles

- AHS continues to support all essential research with health outcome impact
- Resumption of research activity impacting clinical operations or service departments will be determined by the leaders in those areas that support the work
- All research staff working at AHS sites must abide by fit-for-work screening, PPE requirements, public health guidance and any other clinic-specific requirements
- To help maintain physical distancing and minimize people traffic volume, avoid coming into AHS sites if your work can be conducted remotely or continue using HMRC facility
- AHS reserves the right to suspend research studies at any time in any area should AHS require operational resources to be diverted for new outbreaks or demand surges.

Access to Operational Areas

- Urgent requests are being triaged on a case-by-case basis
- The Health System Access (HSA) team is collecting and organizing clinic-specific feedback related to:
 - Capacity to support non-essential research
 - Non-employee personnel limits
 - PPE requirements
 - Allowance for monitoring visits
- Clinic-specific responses for readiness to relaunch will be accessible via [HSA Research Resource](#) page (COVID-19 section)
- Check the requirements of your area on this page prior to planning to come on site
- Health System Access will resume requesting for Operational Approval based on clinic responses

Access to Service Departments

- ✓ Pharmacy services
- Diagnostic imaging
 - ❖ Calgary Zone DI is currently focused on catching up and rebooking their clinical patients, please continue to hold off on non-essential research orders
- Lab services
 - ❖ Some outpatient lab collection sites remain closed
 - ❖ Service centres are operating at reduced capacity to maintain physical distancing requirements
 - ❖ If APL patient kit collections and lab testing are required as a part of the study, it is difficult for APL to accommodate due to diverted processing capacity
 - ❖ Download the latest guidance memo from [APL](#) or [DynaLife](#) and visit the [APL website](#) for updates regarding temporary location closures

CancerControl Alberta

- All researchers wishing to conduct research in CancerControl Alberta (AHS) sites must ensure approval from site Executive Director, who will review requests on a case by case basis
- Considerations include:
 - Operational / clinical capacity
 - availability of adequate space for research activities
 - Plans to ensure adherence to all guidelines that are in place to optimize safety of people at the site
 - Allowance for monitoring visits
- Updated guidance regarding external monitor or vendor access will be forthcoming
- Non-interventional studies should continue to be conducted remotely to limit in-person access to CCA sites

Links & Contact Information



- Session slides and updates will be posted on:
 - [COVID-19 Guidance for Researchers page](#) and [CCCR](#) pages
- UC CCCR & HMRC: sabine.moritz@ucalgary.ca
- UC regulatory support: linda.Longpre@ucalgary.ca
- AHS updates:
 - <https://extranet.ahsnet.ca/teams/AHSRA/SitePages/Home.aspx>
- AHS HSA: becky.wong@ahs.ca

Questions

- Ask questions in the chat
- VPR Comms team will facilitate Q&A
- If we can't get to all questions in the session, we will follow up via email
- A Q&A document will be posted on the UC VPR [COVID-19 Guidance for Researchers page](#) and [CCCR](#) page