COVID-19 Research Response
Guidance for Researchers

April 20, 2020
Marc Leduc & Becky Wong
Key Messages

Refer to full memo here: COVID-19 Memo

Study Submission and Approvals:

• Effective March 26, 2020, all COVID-19-related research with AHS clinical operational impact is subject to approval by AHS’ Emergency Command Centre (ECC).

• Do not initiate any new non-essential clinical studies at this time. Clinician-researchers will exercise clinical judgment to determine if a study is essential.

• You may continue to submit non-critical approval requests, but expect a longer than usual processing time.

• Operational approvals involving Emergency Departments or inpatient areas are suspended until further notice.
Key Messages

Recruitment and Patient Contact:

• In-person recruitment activities for non-essential studies are no longer permitted
• All non-urgent AHS ambulatory (outpatient) clinic visits, including those for research purposes are to be postponed (as of April 1), until after April 30, 2020
• For non-interventional clinical studies, such as those involving surveys or interviews, researchers must use phone or virtual communications to avoid in-person interactions and minimize entry into AHS facilities.
• Ensure all phone or virtual communications are dictated or documented appropriately
Key Messages

Impact on Support Services:

• To alleviate strain on Alberta’s laboratory system, stop non-essential research-related lab testing and consider postponing non-urgent or routine research-related diagnostic imaging procedures

• Essential research lab tests would typically ensure the safety of patients who are receiving investigational medication

• Research staff and study participants who feel unwell or have even mild symptoms of any cold or flu must not enter any AHS facility and must immediately self-isolate and use the Alberta self-assessment tool to determine whether you may need testing for COVID-19
Key Messages

General Remote Access:
• Please minimize entering AHS facilities for data collection
• The HSA IT Access for Research page contains information about requesting remote access to AHS systems
• If you have a university device, please consult with your university’s IT department to discuss VPN options and access to the PartnerApps portal

Monitor Access:
• Research Monitors should monitor remotely as travel and site visits are not permitted at this time
Additional Resources

External COVID-19 Updates:
  ahs.ca/covid
  alberta.ca/covid

Other Resources:
  • AHS Research: ahs.ca/research
  • Health System Access (HSA) SharePoint for Research Specific Resources: https://extranet.ahsnet.ca/teams/AHSRA/SitePages/Home.aspx
  • Northern Alberta Clinical Trials Research Centre (NACTRC) Updates: https://nactrc.ca/news/
  • University of Calgary – Calgary Centre for Clinical Research: https://cumming.ucalgary.ca/research/cccr

U of C IT: https://cumming.ucalgary.ca/about/faculty-and-staff/partnerapps
U of A MedIT: https://www.ualberta.ca/medicine/programs/medit
COVID – 19
UNIVERSITY OF CALGARY
GUIDANCE AND SUPPORT
FOR CLINICAL RESEARCH

Sabine Moritz
Director, Clinical, Health Services and Population Health Research
Overview

1. Guidance & Facilities Update
2. Supports and Initiatives
3. COVID 19 Research
Guidance

Research in AHS Space

- All AHS policies and procedures must be followed including AHS screening requirements (link to latest guidance from AHS on research in AHS facilities).
- Research staff are asked to limit personal contacts, laboratory visits or trips into clinics and hospitals and consider if study visits could be canceled, delayed or held virtually.
- Researchers are asked not to initiate any new non-essential clinical studies. Link to essential research definition.
AHS Approvals

- AHS Health System Access will prioritize the processing of administrative approvals for studies related to essential clinical studies or COVID-19 response and/or treatment testing.

- For non-critical approval requests, please expect a longer than usual processing time, operational approvals involving Emergency Departments and/or inpatient areas will be suspended until further notice.
Guidance

Monitoring visits

- Effective March 27th, on-site monitoring visits are no longer permitted for pharma sponsored as well as investigator initiated trials.

- Monitoring visits can either be deferred or remote monitoring can be arranged. Link to Memo on Clinical Trials Remote Monitoring and Study Status Updates during the COVID-19 Pandemic
REB Guidance

- The CFREB and CHREB advise investigators to consider if their research protocols could be modified or delayed, to limit personal contacts, laboratory visits or trips into clinics and hospitals. Specifically, in some research settings in-person participant interactions could be reduced and/or replaced with telephone or online communication.

- While TCPS 2 typically requires review and approval of modifications prior to implementation, an exception can be made where the change is necessary to eliminate an immediate risk to participant(s) (Article 6.15). Such changes may be implemented but must be reported to the REB at the earliest opportunity (within 5 business days as a guide).
UC Investigational Unit

- The Heritage Medical Research (HMRC) will remain open for essential study visits.
- Operation of the HMRC facility is following AHS guidance.
- Only patients and study staff who pass the AHS screening test will be permitted to enter HMRC. Link to HMRC website.
- HMRC may experience short-term closures due to COVID-19 exposure in its facilities or due to temporary staff shortage.
- The FMC ICU clinical trials unit facility will be unavailable until further notice.
AHS Research Pharmacy

- Located at the U of C TRW Building (adjacent to HMRC).
- Approved as essential service at the U of C (will remain in operation).
- Opportunity to move IP from local hospital pharmacy to central research pharmacy (will require request for TRW building access).
Study Staff Resources for COVID Research: matching of underutilized research staff with COVID studies (coordinated by CCCR)

Central Study Start-up for COVID Research: coordinator pool available for study start up (coordinated by CCCR)

Funding for COVID Research
UC: $500K were offered through the CRF, 7 awards were made. RSO maintains funding opportunities page.

Collaboration:
UC VPR maintains a research collaboration page (Slack work spaces, equipment search, stakeholder liaison, COVID studies list)
COVID-19 Research

- 32 COVID related studies are in start-up or under way.
- Rapid activation through REB, legal and research accounting
- Biosafety Committee authorization is required prior to performing research with the virus causing COVID-19 (including accepting patient samples). Contact biosafety.officer@ucalgary.ca.
• Sabine Moritz (sabine.moritz@ucalgary.ca) requests for study staff resources, AHS liaison, HMRC, CCCR, TRW building access
• Linda Longpre(linda.longpre@ucalgary.ca) regulatory questions and requests for study start-up
• Amanda Mauthe (amanda.mauthe@ucalgary.ca) rapid budget review for COVID studies
Questions & Answers: Summary

**Question 1:** When operational approval is requested for a study from a service area, such as pharmacy, will they only review those applications which are considered essential? What if people are having issues understanding the definition of ‘essential research’, and as it applies to oncology studies for example?

**A:** New study approvals in AHS spaces are being reviewed for their 'essential' or emergency nature. There is also an oncology specific FAQ resource available. Most hematology and oncology research will continue.

Clinical judgement paramount, and researchers are urged to seek advice from leadership – clinical councils or Deans, for example, depending upon the organizational area of research. The University of Alberta specifically recommends that Faculty of Medicine and Dentistry researchers seek advice and assessment via Mark Taylor from the Faculty of Medicine and Dentistry Office of Research.

The ACRC has released a provincial newsletter that includes guidance on essential vs. non-essential research: [https://mailchi.mp/405f177e72c4/clinical-health-research-upcoming-events-282333?e=13644f21fc](https://mailchi.mp/405f177e72c4/clinical-health-research-upcoming-events-282333?e=13644f21fc)

The University of Calgary considers this the definition of ‘essential research’:

A. Research that is part of the Canadian COVID-19 Rapid Response Research Grants Program;
B. Other time-sensitive COVID-19 related research that is vital to dealing with the current COVID-19 pandemic;
C. Clinical Research in which participant health might be put at risk if the program is suspended;
D. Ongoing research in which significant amounts of data would be completely lost or compromised, if the experiment or project was terminated early/suddenly;
E. Research contract work that can be undertaken while meeting COVID-19 safety principles and in which contract deliverables must be met in order to continue funding. Such contracts could be with any external entity, including industry, government or another institution.
Questions & Answers: Summary (cont’d)

Question 2: If a study has been revised to conduct visits / interviews by telephone, what constitutes an acceptable consent methodology?

A: There is an FDA guidance document available specific to informed consent. AHS recommends that researchers speak with their Health Systems Access team advisors. There is also guidance available from the University of Calgary REB regarding verbal consent: https://research.ucalgary.ca/sites/default/files/RSO%20Docs/CHREB/Oral-consent-guidelines-and-COVID-19.pdf

Question 3: How do we connect with AHS advisors about the verbal consent?

A: If you know who your AHS Health System Access Advisors is, you can look up their contact information using this link: https://extranet.ahsnet.ca/teams/AHSRA/SitePages/About%20Us.aspx
If you do not know who your advisor is, please send an email to: research.administration@ahs.ca

Question 4: How can a University of Alberta employee request access to Connect Care or AHS systems?

A: Non-AHS employees can submit their system request via: http://bit.ly/1NTJabJ