

**Date:** **\*\*UPDATED\*\*** April 1, 2020  
**To:** Research teams working in AHS facilities or accessing AHS resources  
**From:** Kathryn Todd, VP – Provincial Clinical Excellence  
Marc Leduc, Senior Provincial Director – Health Evidence & Innovation  
**RE:** COVID-19 Guidance for Researchers

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## Key Points:

### **\*\*NEW\*\***

- Effective March 27, 2020, all COVID-19-related research with AHS clinical operational impact will be subject to approval by AHS' Emergency Command Centre (ECC).
- Ongoing studies can still continue; however, AHS' response to the pandemic may in the future limit its ability to initiate or continue supporting a study. More updates will be provided as needed.
- All research staff and participants are subject to screening prior to entering an AHS facility. No one who has cold or flu-like symptoms such as cough, runny nose or sore throat, loose stool or rash, may enter AHS facilities for research purposes.
- 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.
- Stop non-essential research-related lab testing and consider postponing non-urgent or routine research-related diagnostic imaging procedures.

AHS is providing updated COVID-19 guidance and reminders to all research staff working in AHS facilities, or requiring AHS resources and support for their research studies.

## Overarching considerations:

- 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.
- While remaining self-isolated, please use the Alberta [self-assessment tool](#) to determine whether you may need testing for COVID-19. Even if you do not require testing, you are still required to [self-isolate](#) for a minimum of 10 days if you have a cough, fever, shortness of breath, runny nose, or sore throat that is not related to a pre-existing illness or health condition.
- As always, all AHS policies and procedures are to be followed, including infection prevention and control (IPC) practices, and Workplace Health and Safety rules, when in our facilities. If you have questions, the AHS Health System Access team ([research.administration@ahs.ca](mailto:research.administration@ahs.ca)) can connect you with the appropriate representative for a consultation.
- Please check your AHS email inbox regularly for the latest updates from AHS leadership on COVID-19, and please visit [www.ahs.ca/covid](http://www.ahs.ca/covid).

### **For Current (active) Studies**

- Ongoing interventional studies, such as clinical trials for investigational medications and treatments that provide care and study drugs to enrolled patients, may be subject to your academic institution's approval to continue as long as patient safety can be maintained.
- All research staff and participants are subject to screening prior to entering an AHS facility for research-related appointments. Screening will be implemented by zone and site, based on local requirements, but may involve reporting to a screening station to complete a temperature check and short questionnaire to assess health risks.
- To alleviate strain on Alberta's laboratory system, please cease all non-essential and routine research-related laboratory testing. Essential research lab tests would typically ensure the safety of patients who are receiving investigational medication. Many study sponsors have issued guidance around minimizing lab orders and procedures to submit protocol deviations.
- Researchers should consider postponing non-urgent or routine research-related diagnostic imaging procedures as part of our efforts to reduce the spread of COVID-19.
- AHS care teams are working hard to manage their clinical workloads; please minimize operational impacts or requests for research-related assistance in AHS facilities.
- AHS mandates the practice of social distancing including establishing conservative limits to the number of individuals in a research area at any one time.
- In-person recruitment activities for non-essential studies are no longer permitted.
- 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. Researchers with an AHS network account can visit AHS' [Virtual Health Insite](#) page to learn about [setting up a Basic AHS Zoom](#) account for this purpose.
- Ensure all phone or virtual communications are dictated or documented appropriately.
- Contact your Research Ethics Board of record when revised participant consents or consent addendums are required (e.g. to update privacy considerations with use of different communication channels), or when protocol deviations need to be reported as per REB guidance.

### **New (not yet active) studies**

- Effective March 26, 2020, all COVID-19-related research with AHS clinical operational impact will require approval from AHS' Emergency Command Centre (ECC) before NACTRC/AHS Administrative Approval is issued. The ECC approval process will be coordinated by NACTRC or by AHS' Health System Access team.
- AHS Health System Access and NACTRC continue to prioritize studies deemed essential or those related to COVID-19 response, treatment or testing.
- 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. Essential studies would

typically have significant beneficial impact on patient health outcomes and may be subject to your academic institution's approval prior to initiation.

- For non-critical approval requests, please continue to submit approval requests but expect a longer than usual processing time. Operational approvals involving Emergency Departments or inpatient areas will be suspended until further notice.

### **ConnectCare Access**

If you need to add additional trained research team members to support your study within Connect Care, please email [Research.Adminstration@ahs.ca](mailto:Research.Adminstration@ahs.ca) with the ethics ID and the name of the trained staff member with the header "Urgent: CC Staff Addition".

### **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.

### **Remote Monitor Access**

Research Monitors should monitor remotely as travel and site visits are not permitted at this time.

Should the research team support remote monitoring, instead of reviewing shadow charts or electronic health records, the access is given to certified copies of the health records. When providing certified records, research teams must ensure that:

- They ask the sponsor what they require (avoid sending more information than is required)
- The certified copies are properly de-identified, i.e. ALL IDENTIFIERS (names, initials, MRNs, AHS numbers, etc.) have been removed. Please review the entire document carefully before sending.
- The study ID is written on the top of each page.

The transmission of any health information are subject to patient consent and relevant AHS policies related to access, use and disclosure of information, as well as policies regarding safeguards and protection of information. AHS policies are available at: <https://www.albertahealthservices.ca/about/Page210.aspx>.

While AHS recognizes the importance of rigorous and systematic studies at this time of uncertainty, the response to the pandemic changes daily and, as noted above, may limit AHS' ability to initiate or continue a study.

These guidelines reflect input from the Northern Alberta Clinical Trials Research Centre (NACTRC), Calgary Centre for Clinical Research (CCCR) and Cancer Control Alberta. AHS is currently working with its academic partners for alternatives to providing research care and for continued research access and support. Please stay tuned for additional details.

### **Additional Resources**

External COVID-19 Updates:

- [ahs.ca/covid](https://ahs.ca/covid)
- [alberta.ca/covid](https://alberta.ca/covid)

Other resources:

- AHS Research: [ahs.ca/research](https://ahs.ca/research)
- HSA SharePoint for Research Specific Resources:  
<https://extranet.ahsnet.ca/teams/AHSRA/SitePages/Home.aspx>
- 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>