

Memorandum

Date: **UPDATED** August 27, 2020 (Replaces June 10, 2020 memo)

To: Research teams working in AHS facilities or accessing AHS resources

From: Patty Wickson, Executive Director, Innovation, Evidence, Evaluation & Impact, on behalf of Marc Leduc, Senior Provincial Director, Health Evidence & Innovation

behalf of Marc Leduc, Senior Provincial Director – Health Evidence & Innovation

RE: COVID-19 Guidance for Researchers – Resuming research at AHS facilities

Key Points:

NEW

- AHS continues to work closely with operational areas, universities and sponsors to accommodate and resume as much research activity as possible, while adhering to public health and AHS operational guidelines (<u>summary of AHS</u> operational guidance).
- It is the discretion of each AHS operational area to determine its ability to accommodate non-essential AHS ambulatory (outpatient) research visits; reapproval to access the operational area may be required. Please check the <u>Health</u> <u>System Access Research Resource</u> page for Relaunch Readiness information.
- Alberta Precision Laboratories continues to request that only medically necessary lab work should be ordered at this time; if the ordering physician makes the decision to continue or enroll a patient on a trial, APL will not turn away patients presenting with bloodwork for clinical trials and research.
- There are no restrictions on research-related diagnostic imaging.
- Where possible, research-only visits for healthy research participants or participants without an additional clinical purpose should continue to be conducted online or take place at non-AHS facilities.
- For non-interventional clinical studies, such as those involving surveys or interviews, researchers should continue to use phone or virtual communications to avoid in-person interactions and entry into AHS facilities.
- AHS appreciates the patience and flexibility of investigators and study teams during the pandemic.

AHS provides the following 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 in accordance to guidance found at <u>AHS' COVID</u> page.
- All research staff and participants may be subject to screening prior to entering an AHS facility. No one who has cold or flu-like symptoms may enter AHS facilities for research purposes.
- As always, all AHS policies and procedures are to be followed, including infection
 prevention and control (IPC) practices, Workplace Health and Safety rules, and PPE use
 requirements when in our facilities. If you have questions, the AHS Health System



Access team (<u>research.administration@ahs.ca</u>) 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 <u>www.ahs.ca/covid</u>.

For Current (active) Studies

If your research has been suspended, please check the <u>Health System Access Research</u> <u>Resource</u> page for Relaunch Readiness information of operational areas that have provided relaunch information for researchers. If you do not see your operational area listed and require a contact within the area, please contact <u>Research.Administration@ahs.ca</u>.

If you are uncertain about the conditions for resuming your research and would like to apply for re-approval to access the operational area, please submit your request to NACTRC or to Research.Administration@ahs.ca.

- 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.
 Updates will be provided as required. Please consult with your academic institution to
 discuss possible options for using alternate clinical space based at the universities.
- All research staff and participants are subject to screening and appropriate PPE use
 prior to entering an AHS facility for research-related appointments. Screening and PPE
 requirements will be implemented by zone and site, based on local requirements.
- AHS mandates the practice of physical distancing including establishing conservative limits to the number of individuals in a research area at any one time.
- For non-interventional clinical studies, such as those involving surveys or interviews, researchers should continue to 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 page on Insite 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

- AHS Health System Access and NACTRC continue to prioritize studies deemed essential or those related to COVID-19 response, treatment or testing.
- Please expect a longer than usual processing time for all research approvals. If you require urgent attention to your research request, please submit the REB ID and reason for expediting to Research.Administration@ahs.ca.



General Remote Access

Please minimize entering AHS facilities for data collection. The <u>HSA IT Access for Research</u> 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 originating from outside of Alberta should continue to monitor the studies remotely as travel and site visits are still 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 is 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.

These guidelines reflect input from the Northern Alberta Clinical Trials Research Centre (NACTRC), Calgary Centre for Clinical Research (CCCR) and Cancer Control Alberta. AHS continues to work 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
- 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