Memorandum

Date: **UPDATED** June 10, 2020 (Replaces April 6, 2020 memo)
To: Research teams working in AHS facilities or accessing AHS resources
From: Marc Leduc, Senior Provincial Director – Health Evidence & Innovation
RE: COVID-19 Guidance for Researchers – Resuming research at AHS facilities

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.

**Key Points:**

**NEW**

- AHS appreciates the patience and flexibility of investigators and study teams during the pandemic. For now, processes related to research established earlier in the pandemic remain largely the same. AHS continues to work closely with the universities. In addition to following AHS requirements, please follow your university’s guidance for resumption of services and definition of essential research. Your university may have additional approvals or requirements.
- Continue to postpone non-essential AHS ambulatory (outpatient) clinic visits, including those for research purposes. AHS will re-evaluate the status of the health system’s resources in late June to determine if extension of this timeline is required. Essential services and urgent patient visits will continue to be accommodated. (Summary of operational guidance.)
- Continue to postpone non-essential research-related lab testing and diagnostic imaging procedures.
- Appointments for healthy research participants should take place at non-AHS facilities or online. Research participants coming to AHS facilities must have a critical clinical purpose for doing so. 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.
- While AHS is resuming various services, how AHS clinics and programs operate within the context of the pandemic will be different, and therefore could impact individual research projects differently.
- As always, when a patient asks AHS clinical staff about research studies relevant to their care, they can be directed to bethecure.ca. From there, patients can find information to contact research teams to find out if a specific study is being conducted at an alternate non-AHS location.

**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 AHS’ COVID 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 (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.

For Current (active) Studies

• As stated above, all non-urgent AHS ambulatory (outpatient) clinic visits, including those for research purposes, should continue to be postponed. AHS will re-evaluate the status of the health system’s resources in late-June to determine if extension of this timeline is required. Essential services and urgent patient visits will continue to be accommodated.

• 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. To review site-specific guidance for researchers, please visit HSA’s Research Resource page in the “AHS Research Relaunch Readiness” section.

• To alleviate strain on Alberta’s laboratory system, please continue to hold off on 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. Further clarification is provided in the Alberta Precision Laboratories and DynaLIFE memo.

• Researchers should continue to postpone non-urgent or routine research-related diagnostic imaging procedures. Please refer to AHS guidelines for additional information.

• AHS care teams are working hard to manage their clinical workloads; please minimize operational impacts or requests for research-related assistance in AHS facilities. If uncertain, please check the Health System Access page, Research Relaunch Readiness, or reach out to the clinical area for clarification.

• AHS mandates the practice of physical 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 continue to be prohibited.

• 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

- All COVID-19-related research with AHS clinical operational impact will continue to 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.
- Continue to hold off on initiating 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.
- Please continue to submit non-essential research approval requests, but expect a longer than usual processing time. Operational approvals for non-essential research involving Emergency Departments or inpatient areas continue to be suspended until further notice.

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 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.

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 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