

Date: ****UPDATED**** October 22, 2021 (Replaces August 27, 2020 memo)
To: Research teams working in AHS facilities or accessing AHS resources
From: Marc Leduc, Senior Provincial Director – Health Evidence & Innovation
Becky Wong, Director – Health System Access
RE: COVID-19 Guidance for Researchers – conducting research at AHS facilities

Key Points:

****NEW****

- AHS' [Immunization of Workers for COVID-19 Policy](#) came into effect on September 14, 2021. It requires all employees, medical and midwifery staff, students, volunteers and contracted healthcare providers to be fully immunized for COVID-19 by **November 30, 2021**. This policy applies to all non-AHS employed researchers, including research coordinators, associates or research monitors, who require physical access to AHS facilities.
- AHS has issued a moratorium on approving non-essential research requests led by non-Alberta Principal Investigators or research teams. We will continue to meet the requests of Alberta researchers.
- It is the discretion of each AHS operational area to determine its ability to accommodate non-essential AHS ambulatory (outpatient) research activities, including research monitoring, and re-approval to access the operational area may be required. In addition to the general conditions posted at the [Health System Access Research Resource page](#) related to Research Relaunch Readiness, researchers are expected to adhere to conditions set out within their Health System Access or Northern Alberta Clinical Trials Research Centre (NACTRC) Administrative Approval document.

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 with 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.
- All non-AHS employee research staff members should check their AHS email inbox regularly for the latest updates from AHS leadership.

- AHS appreciates the patience and flexibility of investigators and study teams during the pandemic.

AHS COVID-19 Immunization Policy

AHS' [Immunization of Workers for COVID-19 Policy](#) came into effect on September 14, 2021. It requires all employees, medical and midwifery staff, students, volunteers and contracted healthcare providers to be fully immunized for COVID-19 by **November 30, 2021**. This policy is applicable to all non-AHS employed researchers, including research coordinators, associates or research monitors, who require physical access to AHS facilities.

This policy will protect our vital frontline healthcare teams who continue to provide excellent care to anyone who needs it and protect our patients and the communities we serve. We value our researchers and are grateful for their ongoing work and dedication to support the healthcare system.

“Fully immunized” means an individual has: (a) received two doses of a vaccine considered valid by Alberta Health in a two-dose COVID-19 vaccine series or one dose of a vaccine considered valid by Alberta Health in a one-dose COVID-19 vaccine series; and (b) for whom 14 days have elapsed since the date on which the person received the second dose of the COVID-19 vaccine considered valid by Alberta Health of a two-dose series or one dose of the COVID-19 vaccine considered valid by Alberta Health in a one-dose vaccine series.

Alberta Health has announced that some Albertans are eligible to receive a third dose of vaccine. At this time, a third booster shot is not required to be considered fully immunized for the purpose of the AHS' Immunization of Workers for COVID-19 Policy.

Rapid testing is not permitted as an alternative to being fully immunized.

AHS will not permit non-AHS employed researchers to interact with AHS patients or staff or attend AHS facilities if they are not fully vaccinated due to medical or religious accommodation. AHS requires full compliance with the policy. The employer of any non-AHS employed researcher is responsible for managing the non-AHS employed researcher in accordance with their governance/structure. Non-AHS researcher employers must consult their own legal counsel and other advisors for any issues related to non-compliance by staff, human rights concerns, employment law, or related matters.

Non-AHS employed researchers should **NOT** use the AHS submission form to provide their immunization information. Employers of non-AHS employed researchers will be contacted by AHS Health System Access (HSA) to provide a signed “Declaration of Compliance with AHS Mandatory Vaccine Requirements” prior to **November 30, 2021**. If you are an employer of research coordinators and were not contacted by HSA, please contact Research.Administration@ahs.ca.

For Current (active) Studies

If your research has been suspended, please check the [Health System Access Research Resource 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 Research.Administration@ahs.ca.

If you are uncertain about the conditions for resuming your research and would like to apply for re-approval to access the operational area, 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.
- 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.
- When accessing an AHS site, 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. Ensure all phone or virtual communications are dictated or documented appropriately. 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.
- 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 has issued a moratorium on approving non-essential research requests led by non-Alberta Principal Investigators or research teams. We will continue to meet the requests of Alberta researchers.
- AHS Health System Access and NACTRC are working to process and approve all research study requests.
- AHS' pandemic response and escalation of high priority COVID-related research studies has caused a longer than usual processing time for all research approvals. If your research request requires urgent attention, please submit the request with the REB ID to Research.Administration@ahs.ca.

General Remote Access

Please continue to 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.

Research Monitoring Access

If possible, Research Monitors originating from outside of Alberta should continue to monitor the studies remotely as travel and site visits are still discouraged at this time. If on-site monitoring is necessary, research teams should consult with the manager of the clinical operational area to determine feasibility of in-person access.

To maintain the health and safety of staff and patients, clinical areas reserve the right to limit physical access to their space.

To support remote monitoring, research teams can choose to provide certified copies of health records as an alternative to remote viewing of electronic 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.

Additional Resources

External COVID-19 Updates:

- ahs.ca/covid
- alberta.ca/covid

Other resources:

- AHS Research: ahs.ca/research
- [Health System Access \(HSA\) for research specific resources](#)
- [Northern Alberta Clinical Trials Research Centre \(NACTRC\) updates](#)
- [University of Calgary – Calgary Centre for Clinical Research](#)