

Guidance to Ramp Down Research Involving Participants in Alberta

Considerations for Essential and Non-essential Research

COVID-19 presents new challenges, which may require changes in processes and how to adapt and/or pause research during COVID-19. This document aims to provide guidance into the decision of whether your research is considered essential or non-essential at this time. Always consult your institution for their guidance – contacts are below.

All research does not need to stop. Activities done remotely (planning, writing, literature review, clinical trial feasibility assessment, study start-up activities, remote data collection, data analysis, remote meetings, etc.) can continue during this time as your institution and access allows. Studies with no face-to-face participant interactions such as chart review studies or on-line surveys may continue as approved when resources allow.

ESSENTIAL RESEARCH

Research may be considered essential where serious or immediate harm could be caused to the research participants if stopped. This includes the class of studies that may not have the prospect of high direct benefit but carry the risk of serious or immediate harm if study interactions were to cease.

Examples include:

- Research protocols involving treatments for acute, life threatening health conditions (e.g. some treatment trials for cancers)
- Protocols where stopping the intervention (e.g., some investigational drugs or vaccines or preventative drug regimens) could be harmful
- Protocols which, if stopped, may pose a risk to the research participant.
 - Protocols in which research participants are receiving interventions or clinical care that is very interrelated to their research participation (e.g., test results coming back that might have clinical implications for their care).
 - Some protocols evaluating treatments for chronic conditions (e.g., asthma, hypertension, depression, etc.).
- Protocols involving assessment of the safety or efficacy of an intervention in which, if stopped, the potential societal benefit of the science would be significantly and adversely impacted, for example where a research assessment (blood collection or imaging study) is only valuable if collected at a very specific time. **This should be measured against the risk to participants and staff, including the risk of exposure of COVID-19.**
- Where the PI agrees the research can be conducted in a safe manner that protects participants, research, and the community. **PIs should consider stopping the enrollment of new research participants unless there is a compelling reason.**

While research activities can continue, consideration should also be given to ceasing or limiting in-person interactions. If there is a compelling reason to continue in-person interactions, check with your institution if permission is required from your respective Dean/Chair/Department Head. **PIs should consider pausing the enrollment of new research participants into these studies for the foreseeable future/until indicated otherwise.**

NON-ESSENTIAL RESEARCH

Non-essential research where delays in data collection have limited impact on scientific objectives; protocols in which delays to starting or pausing of research does not substantively impact on research objectives of the research protocol; protocols in which risks to research participants are higher (e.g., potentially exposing elderly vulnerable individuals to COVID-19) and benefits of the study to the participants remain minimal. Types of studies included are cohort and natural history studies.

Examples include:

- Research with healthy volunteers, any minimal risk studies that require research participants to travel, that involve undergraduate students, or that are in a community setting and require direct contact with researchers.
- On-line visits or data collection that does not require participant interaction may continue if appropriate resources are available.

Non-essential research activities should consider stopping enrollment of new participants in studies requiring face-to-face interaction.

OTHER CONSIDERATIONS:

During this unprecedented time, other considerations should be made while conducting research.

- Change of process of investigational product, pharmacy, diagnostic imaging and lab may need to be considered.
- Resources may become an issue. Nurses and other research staff may be working in alternative environments and not have full access to resources, or may be helping in another capacity during the pandemic.
- Temporary modifications made to protocols to accommodate research activities should have appropriate approvals (REB, Dean, Chair, OA etc).
- Flexibility is key. If your study is put on pause, now is a good time to keep engaging with participants through newsletters, touch points, and develop a re-engagement plan for when your research resumes.

WE'RE TO HELP:

Sponsors, institution, REB and AHS Research Administration, NACTRC, CCCR are all here to help with direction in continuing or pausing your research. Also, the ACRC Concierge Service can direct you to the appropriate guidance, contact acrc@albertainnovates.ca.

- [Alberta Health Services - COVID-19 Updates for Researchers](#) (research.administration@ahs.ca)
- [Covenant Health Research Centre](#)
- [University of Alberta](#) and [UofA Research Ethics Office \(HREB\)](#) (contact your Chair/Dean)
- [University of Calgary](#) and [UCalgary Research Ethics Office \(CHREB\)](#) (avpr@ucalgary.ca)
- [Health Research Ethics Board of Alberta \(HREBA\)](#) (info@hreba.ca or call 780-999-679)
- [NACTRC](#)