Information to Ramp Down Research Involving Human Subjects in Alberta During a Pandemic

Considerations for Essential and Non-essential Research

At this tumultuous time in Alberta, you have probably been inundated with communications regarding changes in process and how to adapt and/or pause your research during COVID-19. This document will endeavor to add some guidance into the decision of whether your research should be considered essential or non-essential at this time.

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

EXAMPLES OF ESSENTIAL RESEARCH

Research that can continue include all protocols in which 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.

For example:

- 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
- Essential research can continue if the PI agrees the research can be conducted in a safe manner that protects subjects, research, and the community. **PIs should consider stopping the enrollment of new research participants unless there is a compelling reason.**

Protocols which, if stopped, may pose a risk to the research participant.

For example:

- 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.).

Adapted from *Essential Information to Ramp Down Research Involving Human Subjects* developed by Pitt Research, Human Research \prot3ection, Office of Research Protections, March 31, 2020.

- 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.**

Research activities can continue but should consider ceasing in-person interactions. PIs should get permission from the appropriate Dean/Chair/Department Head if they have a compelling reason to continue in-person interactions. Approved in-person contact can be limited to the minimum necessary. **PIs should consider pausing the enrollment new research participants into these studies for the foreesable future/until indicated otherwise.**

EXAMPLES OF NON-ESSENTIAL RESEARCH

Cohort and natural history studies 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) and benefits of the study to the participants remain minimal.

For Example:

- Research with healthy volunteers, any minimal risk studies that require research subjects to travel, that involve undergraduate students, or that are in a community setting and require direct interaction with researchers.

Non-essential research activities should consider stopping enrollment of new participants in studies requiring face-to-face interaction. On-line visits or data collection that does not require participant interaction may continue if appropriate resources are available.

Other Considerations:

During this unprecedented time, other considerations should be made while conducting research. Resources may become an issue. Change of process of investigational product, pharmacy, diagnostic imaging and lab need to be considered. 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 may be made to protocols to accommodate research activities. These should have appropriate approvals (REB, Dean, Chair, OA etc. Flexibility will be key in this environment. If your study is put on pause, now is a good time to develop a re-engagement plan for when your research resumes.

Sponsors, institution, REB and AHS Research Administration, NACTRC, CCCR all can 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.

Please refer to specific institutional requirements for further information on whether research should be considered essential or non-essential.

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- Alberta Health Services - COVID-19 Updates for Researchers contact research.administration@ahs.ca
- University of Alberta and UofA Research Ethics Office (HREB) contact your Chair or Dean
- University of Calgary and UCalgary Research Ethics Office (CHREB) contact avpr@ucalgary.ca
- Health Research Ethics Board of Alberta (HREBA) contact info@hreba.ca or call 780-999-6792.