Conducting Research in a Pandemic Environment

HREB Guidance Document

This guidance document provides direction on how data collection with human participants can resume during the COVID-19 restrictions. This process may change given the evolving restrictions by the Alberta's Provincial Chief Medical Officer of Health (ACMOH).

Research that can be carried out remotely must continue in this manner wherever possible to minimize personal contacts. In-person participant interactions should be reduced or replaced with remote research (e.g., telephone or online data collection) whenever possible.

Researchers must consider the nature of the protocol, the type of participants engaged in the research, and any additional risk that may arise by replacing in-person with virtual communication. Revised participant consents or consent addendums may be required (e.g., to update with COVID-19 risk mitigation measures and revised privacy considerations if online platforms are used).

Where research staff has symptoms that are not related to a pre-existing illness or health condition (i.e., cough, fever, shortness of breath, runny nose or sore throat) AHS protocols for self-isolation must be followed: https://www.alberta.ca/isolation.aspx

Increased Research-attributable Risk

Researchers seeking to re-launch studies that include in-person interactions or online meeting platforms must inform study participants about any associated. If in-person interactions are resuming, participants should be advised what (if any) impact this may have on them in terms of risk and COVID exposure. Incremental research related risks of exposure may include increased exposure to other people (e.g., patients, participants or people), risks associated with travel (e.g., public transit).

Fairness and equity

Fairness and equity - "*Depending on the participant pool, the change from in-person to remote participation may also introduce new ethics issues related to fairness and equity, where only those with access and ability to participate remotely (e.g. due to internet connectivity, computer/ smart phone availability and capacity) can continue to participate in the research*" (TCPS2 COVID-19 Interpretations)

Participant vulnerability

Participant vulnerability - "*During the extraordinary circumstances of the pandemic, "participants … may be rendered more vulnerable by the nature of the emergency" (Application of Article 6.21). Vulnerabilities can be psychological due to isolation, stress, anxiety, or for economic reasons due to financial burdens of the pandemic or unemployment. Vulnerabilities can also be social in nature due to limited access to critical services, or physical vulnerability due to pre-existing medical conditions or age*" (TCPS2 COVID-19 Interpretations)

Other considerations

- Does resuming the research impose additional burdens on participants (e.g. telecommunications cost) to continue to participate in the research?
- Is the research question still relevant within the context of the pandemic environment?
- Will the pandemic environment impact or alter the representativeness of the participant sample, or the sample plan, and thus its scientific validity?

- Has interruption of the research (i.e., the stopping and resumption due to the pandemic), or the availability of research funds, impacted its scientific validity or feasibility?
- Has the researcher considered new risks attributed to the research as a result of COVID-19 environment?
- Has the level of risk of previously approved research changed?
- Can the researcher maintain a favorable balance of risks and benefits?
- What measures has the researcher taken to mitigate any increased levels of risk?
- Does the researcher expect the vulnerability of the participants to change within the context of the research?
- Are the initial anticipated benefits of research still possible?
- Do alternate consent strategies need to be considered, for example seeking consent over the internet rather than in person?
- Is the information provided to participants as part of the consent process still accurate, or does it need to be updated?
- Does resumption or continuation of approved research introduce unanticipated changes that may increase the level of risk to require informing the participants as part of the ongoing consent process, for example, informing participants about new information, changed procedures, or changed protections that might affect the participants' choice to continue to participate in the research?
- In the case of multi-jurisdictional and international research, is the researcher sufficiently aware of the local COVID-19 circumstances in the other sites to be able to assess any changed level of risk to participants, and how this may affect any proposed changes to the study and its procedures?
- Where research is based on community engagement or research agreements, has the researcher considered how to negotiate or implement any proposed changes (e.g. additional consultation, engagement or permission needed to begin recruitment or resume the research)?
- Are there other community constraints or institutional permissions required to begin recruitment or resume the research?

Risk mitigation

Researchers should consider risk mitigation strategies such as:

- Use of secure, remote interactions/methods where feasible (e.g., phone, Zoom, Microsoft Teams)
- Screening people attending in-person appointments
- Use/provision of PPE for both research staff and research participants (e.g., masks, gloves)
- Use/provision of hand sanitizer for both research staff and research participants (e.g., masks, gloves)
- Single use research apparatus where possible
- Physical distancing measures
- Sanitization of surfaces and multi-use equipment between patients/participants
- Offering multiple methods of data collection (e.g., phone or mail in surveys in addition to online) to account for participants in remote settings
- Disinfecting equipment for research involving physical assessments and use of equipment (e.g., mouthpieces, treadmills, etc.) according to manufacturer's standards.

Risk communication - Consent modifications:

New risk information must be communicated in written or oral form before participants' data collection in physical settings. A written consent form can be used to communicate COVID-related risk information to

already enrolled participants. This should highlight the new information, reference the original consent and provide the participant the choice to either continue with the study or withdraw. Where ongoing consent is obtained orally, it should be documented.

Where some or all interaction will shift to online, research related risks may include privacy and security of the IT/communication platforms used. When switching to online meeting tools or home offices, additional information should be provided in the consent regarding data security provisions. In particular, it is advised researchers use a secure online platform account, for example those that require a password for meetings.

Any changes to study process (recruitment, data collection, consent form) must be submitted as a modification through ROMEO. Changes can be implemented to remove immediate risk in advance of REB approval but should be submitted at the earliest opportunity (within 5 business days as a guide).

Risk communication – New applications:
The onus is on the researcher to satisfy the research ethics board (REB) that the research can proceed during the pandemic. The following are some considerations for new applications submitted in a pandemic environment. Each research is different, and the nature of participant pools varies, so the issues to consider should be tailored on a case-by-case basis. Researchers should consider the following questions when submitting research that involves in-person interactions with participants.

- Can the research involve participants remotely rather than in person?
- Has the researcher considered new risks attributed to the research as a result of COVID-19 environment?
- Can the researcher maintain a favorable balance of risks and benefits?
- Do alternate consent strategies need to be considered, for example seeking consent over the internet rather than in person?
- In the case of multi-jurisdictional and international research, is the researcher sufficiently aware of the local COVID-19 circumstances in the other sites to be able to assess any changed level of risk to participants?
- Where research is based on community engagement or research agreements, has the researcher considered how to negotiate or implement any proposed changes (e.g. additional consultation, engagement or permission needed to begin recruitment)?
- Are there other community constraints or institutional permissions required to begin recruitment?

IMPORTANT: All research participants must complete the Research Activities COVID Screening Form prior to participating in research. The form is available on the ethics and compliance website:
https://www.mtroyal.ca/Research/EthicsCompliance/HREB/GuidanceDocuments/index.htm

Researchers who receive information about a **research participant** who is symptomatic or has tested positive for COVID-19 is to fill out the correct form visitor/contractor. EH&S will contact them. **These forms automatically notify the people who need to know.** Please do not share information about a symptomatic or COVID-19 positive person with anyone else. **Health information is private.**

Please contact hreb@mtroyal.ca with any questions

Useful links
Panel on Research Ethics. COVID-19 Interpretation: https://ethics.gc.ca/eng/nr-cp_2020-09-02.html

HREB Consent Templates https://www.mtroyal.ca/Research/EthicsCompliance/HREB/Consent/index.htm

Web-based Data Collection and Storage
https://www.mtroyal.ca/Research/EthicsCompliance/HREB/GuidanceDocuments/Collecting-and-Storing-Private-Data-Using-Web-Based-Tools.pdf