**CHREB COVID-19 Risk and Consent Requirements**

The COVID pandemic has altered research conduct significantly. To date, to reduce risk of transmission, research interactions have likely been modified, for example moving from in-person interactions to remote interactions or possibly suspended entirely. COVID restrictions are relaxing somewhat but vigilance is still required. The University of Calgary has determined that certain changes must be put in place to reduce risk to participants and staff. More information can be found on the [emergency management site](https://ucalgary.ca/risk/emergency-management/covid-19-response?utm_campaign=redirect&utm_medium=redirect&utm_source=covid-19).

**Increased Research-attributable Risk**

Where studies are relaunching to include in-person interactions, or online meeting platforms, associated risks must be shared with participants. 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. Where participants are visiting UCMC/AHS facilities for clinical reasons and a research interaction is added on, incremental research related risks of exposure may include:

• increased time within a health care facility

• increased exposure to other people (e.g., patients, participants or people)

Where participants are visiting UCMC/AHS facilities for a research interaction only, research-related risks may include:

• risks associated with travel (e.g., public transit)

• time within a health care facility

• exposure to other people

**Other considerations**

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](https://ethics.gc.ca/eng/nr-cp_2020-09-02.html))

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*](https://ethics.gc.ca/eng/tcps2-eptc2_2018_chapter6-chapitre6.html#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](https://ethics.gc.ca/eng/nr-cp_2020-09-02.html))

**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 those 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
* re-assessing the vulnerability of participants in the context of research (e.g., bringing immunocompromised patients into research setting)

**Risk communication - consent modifications:**

New risk information must be communicated in written or oral form before participants visit UCMC/AHS facilities. A written [consent form addendum](https://research.ucalgary.ca/sites/default/files/CHREB%20Word%20Docs/CHREB%20-Consent%20-Addendum%20-template.doc), or discussion script, 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, the CHREB requests that additional information be provided in the consent regarding data security provisions. In particular, it is advised researchers use an institutional online platform account (e.g. Microsoft Teams, Zoom or Skype for Business), require a password for meetings and if recording, ensure data is stored locally.

Any changes to study process (recruitment, data collection, consent form) must be submitted as a modification through IRISS.  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).

Please contact [chreb@ucalgary.ca](mailto:chreb@ucalgary.ca) with any questions