

COVID-19 Risk and (Re)Consent

Re-consenting Research Participants

When is Re-consent Necessary?

Circumstances may arise when it is necessary to re-consent research participants.

TCPS (2018), Article 3.3 states that consent shall be an ongoing process. The researcher has an ongoing ethical and legal obligation to bring to participants' attention any changes to the research project that may affect them. These changes may have ethical implications, may be pertinent to their decision to continue research participation, or may be relevant to the particular circumstances of individual participants. In particular, researchers shall disclose changes to the risks or potential benefits of the research. This gives participants the opportunity to reconsider the basis for their consent in light of the new information.

The COVID pandemic and physical distancing measures have altered research conduct significantly. To reduce risks research interactions have moved from in-person interactions to remote interactions or have been suspended entirely.

Risk consideration

Where studies are relaunching to include in-person interactions, the risk-benefit ratio needs to be reconsidered. 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

Where some interaction will take place online, research related risks may include privacy and security of the IT/communication platforms used.

Researchers should also consider if the risk/benefit balance of a study intervention is altered in the setting of COVID (for example, studies using immunosuppressants).

Risk mitigation

Researchers should consider risk mitigation strategies such as

- continuing to use secure, remote interactions/methods where feasible
- screening participants coming in
- use/provision of PPE (masks, gloves)
- use/provision of hand sanitizer
- single use research apparatus where possible
- physical distancing measures

Risk communication - consent modifications:

New risk information may be communicated in written or oral form. A written consent form addendum, or discussion script, may 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.

Any such changes must be submitted as modifications through IRISS.

Template wording for oral script:

“We have changed our procedures in this study because of the need to keep participants and researchers safe during the pandemic. We are now asking your consent to [describe change in procedure]. Risks associated with this include [describe risks]. Measures undertaken to reduce this risk include [describe risk mitigation]. All other aspects of the study that were described in the original consent remain the same. Do you consent to remain in the study?”

Template for consent addendum:

Where Sponsors require that such changes be documented in a written consent addendum, the CHREB’s Consent Addendum template may be used. Please see the website: <https://research.ucalgary.ca/conduct-research/ethics-compliance/human-research-ethics/conjoint-health-research-ethics-board>