RESEARCH ETHICS OFFICE

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COVID-19 Risk and Re-Consent

Re-consenting Research Participants

The following guidance document applies to research involving human participant interaction in all research settings including on campus, in a community or other field setting.

When is Re-consent necessary?

Changing the circumstances may make it 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. In particular, researchers shall disclose changes to the risks or potential benefits of the research. This gives participants the opportunity to reconsider the basis of their consent in light of the new information. These changes may have ethical implications, may be pertinent to the decision to continue research participation, or may be relevant to the specific circumstances of individual participants.

The COVID pandemic and physical distancing measures have altered the conduct of human participant research significantly. To reduce risks to researchers and participants, many research interactions have changed from in-person interactions to remote interactions. Meanwhile any continued in-person interactions require a number of actions on the part of the researcher in order to reduce the risk of exposure to COVID-19.

Risk consideration

When studies are resuming to include in-person interactions, the risk-benefit ratio needs to be reconsidered. Participants should be advised what, if any, impact this may have on them in terms of risk and COVID exposure. Where some interaction will take place online, research related risks my include privacy and security of the IT/communication platforms used.

Risk Mitigation

Researchers should follow the Chief Medical Officer of Health (CMOH) guidelines.
Some risk mitigation strategies to consider include:

- Continuing to use secure, remote interactions/methods where feasible (e.g. phone, Zoom, Microsoft Teams)
- Screening participants attending in-person activities

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- Use/provision of PPE for research staff and research participants (masks, gloves)
- Use/provision of hand sanitizer for both research staff and research participants
- Single use research apparatus where possible
- Physical distancing measures provided by CMOH
- Sanitization of surfaces and multi-use equipment between participants
- Use of plexiglass barriers or other engineered structures

Risk communication – consent amendments:

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. **A consent template is provided to support this requirement.**

When switching to online meeting tools, the REB requests that additional information be provided in the consent regarding data security provisions. In particular, it is advised that 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.

When ongoing consent is obtained orally, it should be documented.

Any such changes to study process (recruitment, data collection, consent form) must be submitted as study modifications to the REB.

Template wording to include in 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 for 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 this study?*"

Template for consent addendum outlining all new requirements if in-person is provided **here**

Please contact the Research Ethics Coordinator at vwalker@yukonu.ca with any questions.