Considerations for Researchers: COVID-19 Risk and (Re)Consent

The University of Saskatchewan (USask) Biomedical Research Ethics Board (REB) offers the following guidance to researchers who are continuing, resuming or starting research involving human participant interaction. We gratefully acknowledge the University of British Columbia and University of Toronto, whose guidance we modified for use at USask.

Please note the USask Behavioural REB also has specific requirements for resumption of research and for re-consenting in behavioural research. Please refer to the Human Ethics website for information.

When Re-Consent or a specific consent addendum addressing COVID-19 risks may be necessary

TCPS2 (2018), Article 3.3 states that consent shall be an ongoing process. Researchers have an ongoing ethical 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.

Possible heightened risk

Where studies are resuming and in-person interactions are being proposed, researchers need to consider whether their study participants need to be advised of any potential increased risks that they may be exposed to, due to COVID-19. Some possible incremental research related risks may include:

- Risks associated with travel (e.g., public transit)
- Increased time within a health care facility
- Increased exposure to other patients, participants or people
- Increased risks in cases where the study intervention may heighten COVID-19 risks (e.g. studies using immunosuppressants)
- Changes to the inclusion/exclusion criteria

Note: Resumption of in-person research will not necessarily always increase participant risk. Whether it does or not will depend upon the context of the study and the judgement of the Principal Investigator.

Communication of changes to risks in the informed consent process

If new risk information related to COVID-19 is necessary in the context of a specific research study, the information related to the new or incrementally increased risk, may be communicated to research participants 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 with the choice of either continuing in the study or to withdraw.

Where ongoing consent is obtained orally, the process must be documented in the study log. In cases where it is necessary to obtain written ongoing consent (e.g., if a Sponsor requires that such changes be in writing) an addendum may be developed. In either case, it is not necessary to submit a separate post-approval activity to the REB. This information should, however, be conveyed to the USask REB at the time of the next annual renewal, or next study amendment, as applicable.

Suggested COVID-19 Wording for Consent Documents

The information below should be embedded, as relevant, in the appropriate section of the consent form or be provided as a stand-alone section

- Research site is located [insert], under the jurisdiction of [location] public health. We are taking appropriate safety precautions to reduce the risk of spread of COVID-19 and expect you to do the same.
- Researchers will keep you informed and up to date on COVID-related safety requirements and information that may affect your participation (for example, contact information and contact tracing, if applicable).