

## 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 [COVID updates 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 various sections of consent documents or should be provided as a stand-alone section.

- Research site is located [insert], under the jurisdiction of [location] public health. We are taking all safety precautions to reduce the risk of spread of COVID-19 and expect you to follow public health directives as well.
- If you feel that you are from a vulnerable group with respect to COVID-19 effects (e.g., senior (over the age of 60 years), immuno-compromised), please discuss your participation with the research team before consenting. You are under no obligation to participate and nothing bad will happen if you change your mind about participating in the research.
- If the location of the research has changed, appropriate site-specific safety protocols must be followed.
- If the research is conducted on the USask campus, WH&S protocols must be followed.
- We will be collecting personal contact information that we must retain in order to follow up with you and/or conduct contact tracing if you may have been exposed to COVID-19 in coming to the research site.
- Contact information will be kept separate from data collected through the research study to allow for de-identification of the research data (if applicable, as detailed in the protocol).
- You maintain your right to withdraw from the study at any time, including research data (if applicable). If you do withdraw, we will continue to maintain your contact information and will only give it to the Saskatchewan Health Authority if required for contact tracing.
- We cannot guarantee anonymity as the personal contact information identifies you as a participant.