

CHREB Guidelines for Oral Consent

TCPS2 (Article 3.12) states that evidence of consent shall be contained either in a signed consent form or in documentation by the researcher of another appropriate means of consent. Where oral consent is deemed appropriate, the following guidelines apply:

1. Generally, the use of oral consent is suitable for research that is considered of minimal risk to the participant.
2. The procedures used to seek consent must be described within the ethics application.
3. An oral consent must still contain all of the elements required to informed consent. An oral consent script should be prepared and submitted for REB review and approval prior to its implementation.
4. Where possible, a copy of this script, or a parallel information sheet, should be provided to the participant in advance of the conversation. However, documentation should not be left if it may compromise the participant's safety or confidentiality, i.e., specific cultural settings where written documentation is contrary to prevailing norms or may identify a person as a study participant where privacy and confidentiality are paramount.
5. Participants must have the opportunity to ask questions before providing their consent
6. The researcher must document that oral consent was provided. This can be done via written field notes, an audio or video recording, a witness attestation or other available means.

COVID-19 and circumstances where obtaining written or electronic consent is not possible:

Where feasible, consent should be sought by written or electronic means. COVID-related infection prevention and control measures may preclude this in some circumstances. Both Health Canada and the US FDA are permitting consent to be documented by means other than electronic or written in regulated clinical trials. The documentation of consent by written or electronic means usually required under Alberta's Health Information Act may also be waived by the REB.

Where consent will be obtained orally, please request the waiver in your application or modification request (*e.g., In keeping with the AHS/University and Government of Alberta's directives put in place to support continued research while limiting exposure, interaction and transmission during the COVID-19 pandemic, we are requesting approval for waiver of written consent.*). Please provide details of how the oral consent will be sought and documented.

For trials, please review the guidance from Health Canada and/or the FDA as relevant to your study and ensure that consents provided by participants remain fully informed and voluntary.

Health Canada Guidance:

<https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/announcements/management-clinical-trials-during-covid-19-pandemic.html>

US FDA Guidance:

<https://www.fda.gov/media/136238/download>