UNIVERSITY OF CALGARY

Conjoint Health Research Ethics Board (CHREB)

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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. 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. The researcher must document that oral consent was provided. This can be done via written field notes, audio or video recording or other available means.
6. Section 34 (2) of the Health Information Act states that consent for the disclosure of personal health information must be written or electronic. In most cases, oral consent for access to health information would not be permitted, except as described below:

Studies related to COVID-19 where obtaining written or electronic consent is not possible.

1. In studies regulated by Health Canada (usually clinical trials), consent must be visible – either written or electronic. Health Canada waive this requirement but this is considered on an individual case basis, negotiated between the Investigator/Sponsor and Health Canada.
2. The REB can approve a waiver of written consent if it finds that such consent is not reasonable, feasible or practical to obtain. The investigator must justify the waiver request in the application (i.e., *" 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."*).
3. As above, the process for obtaining oral consent must be fully described in the ethics application.
4. Where an amendment is made to an existing study that is COVID-19 related requesting a waiver of written consent, the amendment must reflect that an oral consent will only be obtained during the COVID-19 pandemic and when the pandemic has passed, the originally approved consent process will be resumed.