Queen's REB Guidelines on Remote and Electronic Consent

Queen's University RESEARCH

Queen's REB Guidelines for Remote and Electronic Consent

Version 1.0
07-Jun-2024

Queen's University
Vice-Principal Research
Research, Compliance, Training, and Ethics
355 King Street West
Kingston, Ontario
K7L 2X3
chair.greb@queensu.ca, **hsreb@queensu.ca**
Research Compliance, Training and Ethics

Queen's University is situated on **traditional Anishinaabe and Haudenosaunee Territory**.

Contents

Purpose

The purpose of this guideline is to:

- Provide clear guidance on the use of remote and electronic consent (eConsent) when designing a research study and performing consenting procedures.

Background

Informed consent is one of the key ethical principles as outlined in the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS 2), Chapter 3. Traditionally informed consent was conducted in person between a member(s) of the study team and the potential participant with a written informed consent form being signed by both parties to document the informed consent process. Over time new technologies and social norms have change the landscape of the consenting discussion. Some research can now be conducted virtually, often via online platforms, and therefore the participant and the study team never meet in person during the study. This has meant that the consent process has had to change to adapt to new research methodologies. These changes include the use of remote consent.

Informed Consent

What is informed consent

Per TCPS (2022) Article 3.2: The key to informed consent is that prospective participants understand the information being conveyed to them by researchers. Researchers and REBs should consider how best to convey that information to facilitate understanding. For example, written documentation may be supplemented with audio and/or visual aids or accompanied by video presentations.

Remote Consent

What is Remote?

Remote consent is the process where obtaining consent occurs when the research team and the participant/substitute decision maker are not in the same physical location. Remote consent can be conducted with participants via virtual eConsent, telephone, conference call or video conferencing. Per TCPS 2, Article 3.12: eConsent may be done in person or remotely. Written consent is however in some instances mandatory (e.g per Health Canada regulation or the Civil Code Of Québec). There are other means of providing consent that are ethically acceptable. In some cultures, verbal consent maybe more appropriate. When other means of consent are used, the consent process should still be documented, for example by using a verbal consent log. In addition, it is recommended that a written letter of information with details about the study is given/sent to the participant for their records. Note that in some cases this may not be possible for research design, cultural or safety reasons.

Remote Consent via telephone or videoconferencing

Remote consent can also be conducted with participants via telephone or videoconferencing. When conducting the remote consent discussion over telephone or video conferencing the participant can either be provided with a letter of information that contains all the required elements prior the consent discussion or a verbal consent script containing all the required elements should be created and read to the participants during the consent discussion. This verbal consent process should be documented by the person conducting the consent discussion using a verbal consent log.

Electronic Consent (eConsent)

What is eConsent?

eConsent is a form of remote consent. The eConsent method can include the use of multimedia, for example videos or interactive presentation) to develop an interactive and more flexible informed consent experience that is accessible for diverse learning styles. Examples of eConsent methods include, but are not limited to:

- Videoconferencing/Telephone consent – Video consent using Queen's approved platforms such as MS teams, Zoom. Telephone consent using a Queen's telephone number.
- Pre-recorded videos – Visual and audio presentation of the study (this approach is not recommended by the Queen's Research Ethics Office).
- Pre-recorded Audio – Voiceover of the consent document (this approach is recommended if used as an aid in interactive consent).
- Email Consent- Consent form/letter of information in written form is sent to the participant electronically, often via an online platform.

Use of eConsent methods and platforms will be reviewed by the REB on a case-by-case basis however any eConsent must contain all the required elements per the applicable consent template and the platform(s) being used must met all privacy and security requirements. In addition, the eConsent must be documented in a way that can be audited by the REB and any other regulatory authority.

NOTE: Any material that is being presented to the participant during the consent discussion needs to be submitted and approved by the REB.

Considerations in the use of Remote Consent via telephone or videoconferencing

- During telephone or videoconferencing consent, participants should be given enough time to ask questions. The verbal consent script should include pauses and spaces for participants to ask questions.
- The consent discussion, over phone or video conferencing, should be conducted in a location that is quiet and allows for privacy for both the participant and the study team.
- The participants should be provided with a written letter of information either prior to or directly after the consenting process. This can be sent via email (using a secured link) or regular mail.
- For regulated studies remote consent must follow all the regulatory requirements.
- For video conferencing Queen's IT approves the use of Queen's zoom and Microsoft teams. If you plan to use another platform they will be reviewed by the REB (and sometimes Queen's IT) on a case by case basis. If an online platform is used that is not supported by Queen's IT, the researcher is recommended to undergo a security activation process (SAP) through IT. The researcher understands that they agree to the risk of using a non-approved platform.
- The consent discussion should not be recorded.

Remote Consent via Email Contact

eConsent occurs when the consent form/letter of information in written form is sent to the participant electronically, often via an online platform, and they provide consent electronically.

For low-risk studies, such an anonymous survey, electronic consent can be completed using implied consent where a consent statement is presented to participants and they agree to participation without verbally speaking to someone.

For higher risk studies or for studies where the participant's name is required to be associated with the consent an electronic signature should be used. Note that email is not a secure way for electronically signed consent to be sent as email communication can easily be intercepted. If a signed consent is being sent, then it must be encrypted and password protected. Queen's OneDrive can be used to send signed electronic consents using the controlled permissions function.

Considerations in the use of Remote Consent via Email Contact

- The electronic consent form/letter of information must contain all the required elements as outlined in the applicable Queen's consent template and must be compliant with all regulatory requirements.

- For Health Canada regulated studies the use of electronic consent is generally acceptable if all regulatory requirements are met. The system must be validated, the consent must contain all required elements and the consent must be sorted for 15 years per Health Canada regulations.
- Online platforms can be used if they meet the requirement listed above and they meet Queen's privacy and security requirements. At Queen's two platforms are approved by IT for electronic consent Queen's Qualtrics and RedCap. However other platforms may be used and will be reviewed by the REB (and in some cases IT) on a case-by-case basis. If an online platform is used that is not supported by Queen's IT, the researcher is recommended to undergo a security activation process (SAP) through IT. The researcher understands that they agree to the risk of using a non-Queen's approved platform. More information about the SAP can be found here: https://www.queensu.ca/its/security-assessment-process.

Health Canada and US regulated studies and documenting consent

Type of regulated study	Acceptable methods of documenting consent
Health Canada regulated studies	- Written signature on paper copy in person, via secure file transfer or registered mail. Note that the best practice for sending signed consent via mail is to provide participants with a stamped and addressed envelope that they can use to return the consent. The use of register mail is best practice, but regular mail can be used if justified. - Electronic signatures using approved electron signatures software/platform. - When consent can't be obtained in person, sponsors should consider other methods, such as over the telephone, or video-teleconferencing. ensure that in cases of verbal consent, a witness (can be a family member) is present and signs an attestation - it must be clear that the witness was present during the process regardless of the method of communication (for example, can be on a conference call) - a scanned copy of the attestation may be forwarded to the investigator by

	email, or a picture of the signed attestation may be sent by email or text - the conversation should be recorded if it isn't possible to have a witness (this recording becomes part of the trial records) - At the first in-person visit, participants should bring the original signed LOI/CF that was previously discussed remotely. At this time, the person who conducted the remote discussion should sign and date the original LOI/CF that was signed by the participant during first virtual (alternative) visit. - A copy of the signed LOI/CF should then be given to the participant and the original should be filed as per record retention requirements. - For more information consult: https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/announcements/management-clinical-trials-during-covid-19-pandemic.html.
US Federally Funded or FDA Regulated Research	– -Written signature on paper copy in person, via secure file transfer or registered mail. Note that the best practice for sending signed consent via mail is to provide participants with a stamped and addressed envelope that they can use to return the consent. The use of register mail is best practice, but regular mail can be used if justified. – -Electronic signatures using approved electron signatures software/platform. – -Verbal consent can only be used if the requirement s for a Reb waiver of written consent as outline in 21 CFR 21 CRF 56.109(c) (For FDA regulated

	research) or 45 CFR 46.117 (c) (for US federally funded research) are met.