Guidance on Electronic Consent[i]

Purpose

This guideline outlines the circumstances and considerations for the ethical review of the use of electronic consent forms for research with human participants at Island Health by the Research Ethics Boards (REBs).

Background

Article 3.12 of the TCPS 2 2018 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." Written consent in a signed statement is mandatory in some cases such as in the Health Canada's Food and Drugs Act. Health Canada may waive this requirement but this is considered on an individual case basis, negotiated between the Investigator/Sponsor and Health Canada.[ii] The consent must be visible, but it may be in written (paper) or electronic form. British Columbia's (BC) Freedom of Information and Protection of Privacy Regulations (FIPPA) section 11(1) (a) states that consent must be in writing. However, both Federal and Provincial BC legislation permit electronic documentation and electronic or digital signatures in most instances, including informed consent for research. (The Federal legislation is the Personal Information and Electronic Documents Act (PIPEDA), the Provincial BC legislation is the Electronic Transactions Act.) There is no Canadian or BC specific guidance pertaining to use and implementation of an electronic informed consent process for research. The ICH-GCP's E6 5.5.3 address electronic data handling which includes electronic informed consent when utilized in the context of a regulated clinical trial.

For Regulated Clinical Trials

Clinical Trials BC (CTBC), Fraser Health and Research Ethics BC (REBC) have issued a document called "Guidance Notes and Refe0gulatory Requirements for Informed Consent in Research During a Pandemic: COVID-19". Their recommendations for electronic consent in the context of a regulated clinical trial state:

"*Electronic Consent must be established in the environment and must meet the record keeping and validation requirements.*

- *The system must be properly validated (ICH E6 5.5.3), with documented procedures and appropriate training*
- *All required elements (C.05.010(h); ICH E6 4.8.10) must be present in the informed consent form*
- *The information must be kept for 25 years (C.05.012(4))*
- *The process for obtaining informed consent using an electronic form should also be well detailed in an SOP."*

Additional suggested requirements include:

- *Have an electronic-Informed Consent (e-IC) training module*
- *Feature instructions for participants at an appropriate reading level with explanation that it is the equivalent of a handwritten signature on paper*
- *Be accessible and usable by all participants in the study*
- *Contain an audit trail*
- *Feature a validated internal or linked signature authentication component*
- *Control for access and passwords*
- *Be remotely or directly accessible for audit, monitoring and inspection*

The US Food and Drug Administration (FDA), the Office for Human Research Protections (OHRP) and Department of Human and Health Services (DHHS) have issued a joint guidance on the Use of Electronic Informed Consent. University of British Columbia (UBC)'s Clinical REB guidelines have adopted most of their recommendations.

For Clinical Studies That Are Not Regulated Clinical Trials

Island Health REBs will permit the use of an electronic informed consent process, provided that it meets fundamental record keeping (including privacy), and validation requirements. These requirements do not apply to completion of anonymous on-line surveys or when implied consent is permissible.

In brief, this means that:[iii]

1. The informed consent must contain all of the elements of informed consent required by the Tri Council Policy Statement (TCPS2) 2018 guidelines and the appropriate REB consent template (clinical or socio-behavioural).
2. The electronic informed consent may be used to supplement or replace paper based informed consent processes.
3. If any or all of the consent process takes place remotely and is not witnessed by study personnel, the electronic system must include an authentication method to ensure that the person electronically signing the consent is the person who will be participating in the study, or who is the person's legally authorized representative. If the person signing is the participant's

legally authorized representative, the consent should indicate what the specific legal authorization is, e.g. committee, legal guardian, etc.

4. Whether the electronic informed consent is obtained from the participant on-site or remotely, there must be sufficient opportunity for the participant to consider whether to participate and there must be a process in place that allows the participant to ask questions about the study both before signing as well as during the participant's involvement in the research.
5. Where appropriate, there must be a process in place for notification of participants of significant new findings.
6. The procedure may include an electronic method to capture the signature of the participant or the participant's legally authorized representative. The REB will recognize an electronic signature that meets the legal requirements applicable to the study: e.g. the Electronic Transactions Act, the Personal Information Protection and Electronic Documents Act; or for regulated clinical trials the ICH-GCPs E6 (as above); or the US FDA regulations (21 CFR part 11), as applicable.
7. As with paper consent processes, participants must be provided with a copy of their electronic informed consent but this can be accomplished through electronic means.
8. The electronic system that supports the electronic informed consent process must be secure, with restricted access and should include methods to ensure confidentiality regarding the participant's identity, study participation and personal information after informed consent has been obtained.
9. If using a participant's personal email address to communicate with them about the consent process, please ensure that you or your institution have already received permission to use that email address to transmit personal information to them which may include their name, health conditions, etc. Please also ensure that you follow any institutional operational policies that may be in place for the use of email. Note: Professional contact information is not considered personal information under FIPPA. The Act defines contact information as "information to enable an individual at a place of business to be contacted and includes the name, position name or title, business telephone number, business address, business email or business fax number of the individual".

   Sample language for consent to use personal email address, which can be used for research purposes including e-consent:
   We are asking to collect your email address because XXX explain why XX. You need to know that emails sent to some webmail services (e.g. Gmail, Hotmail, etc.), may be stored/routed outside of Canada (for example, in the United States) and governed by foreign laws. Due to the fact that future emails will contain personal information about you, including your name and information about your health, the Freedom of Information and Protection of Privacy Act requires that we obtain your consent before we continue.

All of the information, which you provide to us, will be kept completely confidential. Providing your email address means that you voluntarily agree and give your consent for the study team to use email to communicate with you.

10. Information to include in your Research Ethics Application
    i. How will the research team review and consent the participant to ensure that the consent obtained is properly informed?
    ii. How will the consent be given to the participants, how will they access the electronic form? If participants are e-mailed a link to complete the consent form, please attach the email template for review. Include how participant's questions may be answered.
    iii. How will the consent form be signed?
    iv. How do you propose that the form be returned once signed / completed both to the participant and to the study team?
    v. Clarify whether any personal identifiers are captured and stored, e.g. IP address, e-mail address.
    vi. How are electronically signed documents received and stored? Confirm that the completed e-Consent forms will be kept separate from the de-identified study data.
    vii. Attach screenshots or e-consent URL for REB review.

For additional clarification and guidance, please contact the Research Ethics & Compliance office at researchethics@islandhealth.ca.

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[i] University of British Columbia Office of Research Ethics, Clinical Research Ethics Board Guidance Notes, Guidance on electronic consenting link

[ii] University of Calgary Conjoint Health Research Ethics Board guidelines link

[iii] Adopted from "Use of Electronic Informed Consent" Questions and Answers", December 2016 guidance from the DHHS and the US FDA link