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BC Cancer Research Ethics Guidance on E-Consent

NOTE: the use of e-consent for HC and FDA regulated clinical trials requires specific considerations – see page 3 below for details.

Obtaining informed consent from a participant is generally part of most (but not all) research projects. The most common method is to provide the participant with a written paper based document - an informed consent form (ICF) which the participant (or their legal representative) then signs with a 'wet ink' signature as confirmation that they understand the components of the research and agree to participate in it. A copy of the signed consent is then provided to the participant with the original filed in the research records.

It is also possible for consent to be obtained via an electronic process which is known as 'e-consent'. It is important to note that, while the tools used to aid in the delivery/management of the consenting process may differ (i.e. paper-based/hard copy v electronic platform accessed on a computer, mobile phone, or tablet, and/or may include multimedia components) the information required to be provided to the participant must still contain all of the required elements set out in applicable national or international policies/regulations (i.e. TCPS 2, ICH, Health Canada, and FDA). Specific local institutional requirements must also be met, for example, the BC Cancer ICF templates must be followed (if applicable). Updates and amendments must be done to reflect changes in the research and approved by ethics boards for both paper based and electronic ICFs.

The use of e-consent is also not meant to replace ongoing discussions with the participant – consent is an ongoing dialogue between the participant and study team throughout the lifecycle of the project. Further, an e-consent process still needs to be tailored to the risks and complexities of each project, and the use of e-consent may actually result in more complications to the consent process if there is an absence of direct, in-person contact. Alternative methods for the provision of information and/or documentation of consent should always be made available for those unable or unwilling to use electronic methods. Finally, the use of e-consent must also include consideration for non English-speaking participants (see the BC Cancer Research Ethics Board's Guidance on the Use of Interpreters and Translated Documents).

In terms of technical aspects, e-consent needs to be setup on a per project basis, and this is entirely the responsibility of the researcher. BC Cancer Research Ethics can only provide advice in relation to technological options that may be available in relation to the PHSA/C&W Research Electronic Data Capture (REDCap) platform. REDCap offers a digital method to acquire and store participant consent through an e-Consent Framework and PDF Auto-Archiver.

There are a number of options for participants to confirm their consent, eg by 'signing' their consent by typing in their name, by utilizing REDCap's 'Signature' field type on the consent

form, or by using a simple 'I consent' checkbox. The BC Cancer REB prefers that the 'I consent' checkbox is utilized because the first and last name of the participant are already collected during the process, and to add a signature increases the number of identifiers that are attached. The REDCap e-Consent Framework provides standardized tools to obtain consent and uses a storage function which automatically generates a 'hard-copy' PDF of the signed form. The 'Auto-Archiver + e-Consent Framework' option provides a certification page that displays an in-line PDF copy of the document in which the participant will be asked to confirm that all information in the document is correct. The consent process will not be considered complete until they fulfill the certification step. Upon completion, a static copy of their responses in the form of a consent-specific PDF will be stored in the project's File Repository within the local instance of REDCap.

At the time of writing of this document, the PHSA/C&W REDCap platform is the only one within the PHSA/BC Cancer/UBC research communities that satisfies all provincial and institutional requirements relating to privacy and security. BC Cancer Research Ethics supports the use of the PHSA/C&W REDCap platform for use in research projects that are <u>not</u> regulated clinical trials, e.g., biobanks, surveys, questionnaires, etc. (see page 3 in relation to regulated clinical trials). Should a study team wish to utilize a platform other than the PHSA/C&W REDCap platforms, it is the study team's responsibility to undertake necessary steps to ensure the system adheres to all applicable legal and institutional privacy and confidentiality, compliance, and security requirements (please see http://www.phsa.ca/researcher for information on the various requirements). Documentary evidence verifying and confirming that the system meets all applicable requirements must be provided as part of the research ethics submission.

The following information about the e-consent process should be provided:

- if there will be an e-signature and the nature of this e-signature (e.g., an image of the participant's signature, a check box, etc.)
- whether the e-consenting process will be onsite or offsite
    - If onsite, the investigator is responsible for verification of the identity of the participant or legal representative
    - If offsite, the method used to ensure that the person signing the e-consent form is actually the participant or their legal representative
- how the participant will have any questions answered prior to agreeing to participate
- a summary of the training that will be provided to the participant on use of the e-consent form and its equivalence to a paper form
- an explanation about how the participant will get a copy of the informed consent document (e.g., hard copy vs. electronic), and if this will include their e-signature
- how 'ongoing' consent will be obtained, in particular, if any changes are made, how will these be communicated to the participant and, if necessary, how will the participant be re-consented
    - note: as in all research, if changes to the research study are proposed, research ethics approval must be obtained prior to implementing the changes
- if the e-consent contains links to webpages or other documents, the hyperlinks should be maintained and information should be accessible until study completion
- plans for participants who may not wish to utilize e-consent, do not speak English or are visually impaired

- if you are not using a pre-approved platform, an overview of how privacy and confidentiality of the participant will be protected in the system (e.g., use/capture of personal identifiers, encryption methods, etc.).
- the archival and retention process. All research ethics approved versions of the e-consent must be archived and retained for the purposes of auditing.

Regulated Clinical Trials

In addition to the above considerations, regulated clinical trials have specific system 'validation' requirements that must be met, again on a per project level. The UBC Guidance on Electronic Consenting discusses the use of electronic consenting in regulated clinical trials - https://ethics.research.ubc.ca/sites/ore.ubc.ca/files/documents/E%20consent%20final%20April%2029%20with%20links.pdf

As noted in the UBC Guidance, there is no Canadian or BC specific guidance pertaining electronic consent processes for research but UBC references the ICH-GCP's E6 5.5.3 for direction, and BC Cancer Research Ethics also adopts these requirements. These are set out below for ease of reference:

- The system must be properly validated (ICH E6 5.5.3), with documented procedures and appropriate training
    - Please note, it is the responsibility of the trial team to validate the system and the project-specific database – BC Cancer Research Ethics will not be involved in this
- All required elements (C.05.010(h); ICH E6 4.8.10) must be present in the informed consent form
    - As above, BC Cancer informed consent template/s must be followed (this template contains all required elements)
- 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 a SOP.
    - Please note, it is the responsibility of the trial team to develop the SOP

While the following are stated to be "additional 'suggested' requirements", BC Cancer Research Ethics' position is that these elements are required.

- Have an e-IC training module for the trial team
    - Please note, it is the responsibility of the trial team to develop a training module, not BC Cancer Research Ethics
- 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 (e.g. if REDCap was the system proposed, teams will need to create a workflow outside of REDCap to validate identity of the signatory)
- Control for access and passwords
    - The electronic system that supports the electronic consent and signature, must be secure with restricted access, and must maintain confidentiality and privacy regarding the participant's identity, study participation and personal information

after the consent has been obtained. The electronic system must encrypt the participant's name and personal information.

- Be remotely or directly accessible for audit, monitoring an inspection

Finally, the above elements must be considered alongside ICH E6(R2) Section 4.8.8 which states "*Prior to a subject's participation in the trial, the written informed consent form should be signed and personally dated by the subject or by the subject's legally acceptable representative, and by the person who conducted the informed consent discussion.*"

In summary, it is the responsibility of the study team and/or sponsor to undertake all processes/procedures relating to system validation requirements for regulated clinical trials on a per project basis. BC Cancer Research Ethics will not assist with or be involved in any system validation requirements, nor will it recommend a specific e-consent platform for use in regulated clinical trials. Further, while the BC Cancer REB may grant a Certificate of Approval to a project that proposes to utilize an e-consent process, this approval should not be viewed as confirmation that regulatory validation requirements have been met. Regulated clinical trials are subject to monitoring/auditing that is outside the purview of the BC Cancer Research Ethics, and these monitors/auditors may differ in their opinions as to whether all applicable compliance requirements have been met in relation to system validation.

Resources

UBC Guidance on Electronic Consenting
https://ethics.research.ubc.ca/sites/ore.ubc.ca/files/documents/E%20consent%20final%20April%2029%20with%20links.pdf

Department of Health and Human Services (HHS), Office for Human Research Protections (OHRP), and the Food and Drug Administration (FDA): Use of Electronic Informed Consent in Clinical Investigations – Questions and Answers Guidance for Institutional Review Boards, Investigators, and Sponsors (December 2016)
https://www.fda.gov/regulatory-information/search-fda-guidance-documents/use-electronic-informed-consent-clinical-investigations-questions-and-answers

ICH Harmonized Guideline, Integrated Addendum to ICH E6(R1): Guideline for Good Clinical Practice E6(R2)
https://database.ich.org/sites/default/files/E6_R2_Addendum.pdf
REDCap: https://rc.bcchr.ca/redcap/