Guidance document on the development and use of an Electronic Informed Consent (eIC)

Introduction

This document provides a general guideline and checklist, applicable to clinical trials and research projects on the development and use of an electronic informed consent (eIC) to convey information related to the study[1] to potential study's participants and to obtain participants' electronic consent[2].

In Switzerland the eIC can make use of electronic media (e.g. video, podcasts, interactive websites, applications for tablets and smart phones, etc.) to convey the information. The study participant's consent can be documented either on paper with a hand-written signature or with an electronic signature of both the study participant and the investigator, or of the person authorized to conduct the informed consent process.

In order to be valid, the electronic signature on the eIC should meet the expectations stated below[3] regarding authentication, timestamp of the signature, non-repudiation and unbreakable link:

- authenticate the signatory (i.e. the study participant and the investigator/the person conducting the informed consent process and authorized to sign the eIC), establish a high degree of certainty that the eIC was signed by the claimed signatory;
- provide a timestamp, i.e. that the date, time, and time zone when the signature was applied are recorded;
- ensure non-repudiation, i.e. that the signatory cannot later deny having signed the eIC;
- ensure an unbreakable link between the eIC and its electronic signature, i.e. that the contents of a signed and by the Ethics Committee approved version of the eIC cannot later be changed by anyone without the electronic signature being rendered visibly invalid.

Further functionalities/requirements of the eIC are given in the checklist further below.

Examples of methods used to create valid electronic signatures include, but are not limited to, the use of computer-readable ID cards, biometrics, digital signatures, and username and password combinations of validated systems.

When the study participant signs the eIC at the study site, it should always be possible to verify the identity of a study participant with documentation available to the investigator, of the person conducting the informed consent process. Where electronic consent is given remotely, and the study participant is required to visit the study site for the purposes of the study, verification of the study participant should be done in person e.g. by using information from an official photo identification (e.g. personal identification card, passport, …). The verification must be documented, appropriately filed and archived at the end of the study, and available for audits and inspections.

[1] Throughout the document, for sake of simplicity only the generic term "study" is used, which includes the legal terms clinical trial and research project.
[2] Electronic signatures of study participants on eIC are allowed as of the entry into force of the revised HRA-ordinances on November 1, 2024.
[3] If the requirements change, swissethics will update this guidance document accordingly.

The applicant must submit the same eIC materials to the Ethics Committee that will be presented to the study participants to obtain their consent for participation in the study. I.e. copies of all forms and informational materials in PDF format, with a link to the eIC web page to access videos and web-based presentations. The requestor should also provide transcripts in PDF format of the eIC audiovisual presentations. If the eIC is available as an application (App) for smart phones or tablets, which may or may not include the feature for the electronic signature, the requestor should provide the link to the web page for downloading the App.

The eIC may be subject to updates and changes during the course of the study. In addition to revisions to the text of the eIC, changes made to the computerized systems may alter the validity of the eIC / informed consent process. While the investigator is ultimately responsible for the informed consent process, the sponsor of the study is responsible for the validation and operation of the computerized system used for eIC throughout the study and for providing adequate documented evidence of applicable processes. The sponsors may supply, store and/or manage and operate the computerized system (including software and hardware) directly, or via a service provider. But also in the latter case the sponsor retains responsibility[4].

Consult the guidance document «Notification of significant changes and other changes to the ethics committee» published on swissethics.ch/templates-checklists/notifications for a comprehensive list of changes during the course of the study that need to be reviewed and approved by the Ethics Committee before they can be implemented.

In case of doubts, it is recommended that the investigator or the sponsor of the study discusses plans for using an eIC with the Ethics Committee prior to finalizing the development of the eIC[5]. This in order to ensure that the Ethics Committee agrees that the format may be used to convey the information to the study participants and to obtain the electronic signature, either at the study site or remotely, since for example, obtaining consent remotely may not always be suitable for some studies.

[4] It is important to note that the sponsor has the responsibility for the computerized system used, but the confidentiality of the study participants must be guaranteed at all times. Only sponsor's or service provider's trained monitors (CRAs) can access the study participants for monitoring purposes.

[5] An electronic patient information and/or an electronic consent may not be suitable for certain types of studies. A guide on how to define and design the right eConsent for a particular study and how to generate effective and comparable study data on eConsent is available here.

Points to be considered / requirements in the development and use of an eIC (checklist)

Nr.	Points to consider	In place	References (document, software, App., etc.)	Comments
1	**Computerized systems used for eIC**			
1.1	The sponsor must ensure that programs/systems used for eIC are validated for completeness, accuracy, reliability, consistent performance, and intended use.	Yes □ / No □		
1.3	A system is in place to ensure data integrity throughout and after termination* of the study, for example when making changes to the computerized systems, such as upgrades or migration of the data. *see also 4.3, 5.4	Yes □ / No □		
2	**eIC**			
2.1	The content of the eIC complies with Swiss law (section 2 HRA; section 3 ClinO, art. 8 HRO).	Yes □ / No □		
2.2	The electronic system should provide a clear option to accept or decline the consent.	Yes □ / No □		
2.3	The signed eIC must contain the printed name of the signatory (i.e. the study participant and the investigator/the person conducting the informed consent process and authorized to sign the eIC), the date and time when the signature was executed, and the meaning associated with the signature.	Yes □ / No □		

2.4	A process/system is in place to ensure that the eIC process is appropriate for study participants with impaired motor skills, poor eyesight, lack of familiarity with electronic devices, etc.	Yes □ / No □		
2.5	If an interactive computer program is used, this is appropriate for the intended audience (study participant's age, language, comprehension level).	Yes □ / No □		
2.6	Irrespective of the media used for the signature, either on paper or electronically, in case a signature is applied on a different document (electronic consent page) or only on part of the electronic information (e.g. signature page of the eIC), there should still be an unbreakable link between the electronic information to be signed and the electronic consent containing the signature.	Yes □ / No □		
2.7	The Ethics Committees are required to assess the period of reflection between receiving and signing the eIC as being "appropriate" for the study participants to have sufficient time to consider the implications as part of their review (art. 51 para. 1 HRA). Ensure that eIC will allow for capturing this information or that there is built-in functionality to ensure that lag-time requirements are met before signatures are allowed.	Yes □ / No □		
2.8	At the end of the eIC process, a paper or electronic copy of the signed eIC is given to the study participant. The wet-ink signed original consent or the printed certified copy of the electronically signed consent must be filed in the investigator site file.	Yes □ / No □		

2.9	There are procedures and processes in place for the study participant to withdraw his/her e-consent. If the study participant withdraws from the study through the computerized system for eIC, it must be ensured that such a withdrawal of consent generates an alert to the investigator in order to initiate the relevant steps.	Yes □ / No □		
3	**Remote / on-site access**			
3.1	The eIC material is accessible at the investigational site and remotely.	Yes □ / No □		
3.2	A system is in place to ensure that the study participant has the opportunity to ask questions and receive answers prior to consenting to participate in the study, even if he/she accesses the eIC remotely.	Yes □ / No □		
4	**Data protection, confidentiality and retention**			
4.1	A validated system is in place to ensure study participant's privacy, when electronic communication tools are used as part of the eIC interview process.	Yes □ / No □		
4.2	A validated system is in place to ensure that the study participant's data is stored securely when tools are used as part of the eIC interview process.	Yes □ / No □		
4.3	A system is in place to ensure that the original eIC and the signed paper consent form or the signed electronic consent form are archived appropriately and securely at study end[6] and that it can be retrieved	Yes □ / No □		

[6] The retention time is the following: 20 years for clinical trials conducted under ClinO, Art. 45. 10 resp. 15 years for clinical trials conducted under ClinO-MD Art. 40. 10 years for research projects conducted under chapter 2 HRO, Art. 23a.

	easily and be readable (e.g. by archiving the operating system and applications).			
5	**Amended eIC**			
5.1	A validated system is in place to track changes to the eIC with audit trail capability. i.e. the system tracks any revisions to the eIC, the identity of the person making the changes, the reason for the changes and the date the changes were made. The original data is not deleted or overwritten by the changes.	Yes □ / No □		
5.2	A system is in place to ensure that approved amendments to the eIC are timely transmitted to the study participant.	Yes □ / No □		
5.3	A process is in place to ensure the study participant is given an adequate opportunity to ask questions about the amended content.	Yes □ / No □		
5.4	A system is in place to ensure that the original amended eIC and the signed paper form or the signed electronic form of the amended IC version are archived appropriately at study termination[2] and that all amended versions can be retrieved easily, if necessary (e.g. by archiving the operating system and applications).	Yes □ / No □		
6	**Others**			

6.1	All versions of signed and dated eIC are available to the study participant for the duration of and after the study, either in paper or in electronic form.	Yes □ / No □		
6.2	The eIC is available in paper or electronic form for reviews, audits and inspections.	Yes □ / No □		

Note: If the investigator/sponsor considers appropriate, questions could be added to the eIC (e.g. at the end of each section) to help the study participant understand the content of the eIC material. If questions are added to the eIC, the questions should in no way be intended and/or used as an eligibility test for participating in the study, but only used to help identifying difficulties of understanding and resolve them. Additionally, a validated electronic system should be put in place to ensure that the interactive responses by the study participant are not altered.

Place and date:

Signature:

Definitions

Electronic informed consent, eIC: Use of electronic systems and processes that may employ multiple electronic media (e.g. text, graphics, audio, video, podcasts, passive and interactive web sites, biological recognition devices, card readers, etc.) to convey information related to the study and to obtain and document informed consent. In Switzerland the study's consent can be documented either on paper with a hand-written signature, or with an electronic signature.

Validation of computerized systems: A process of establishing and documenting that the specified requirements of a computerized system can be consistently fulfilled. Validation should ensure accuracy, reliability and consistent intended performance, from design until decommissioning of the system or transition to a new system (ICH GCP 1.65).

Certified Copy: A paper or electronic copy of the original record that has been verified (e.g., by a dated signature) or has been generated through a validated process to produce an exact copy having all of the same attributes and information as the original (ICH GCP 1.63).

Electronic Signature: A computer data compilation of any symbol or series of symbols, executed, adopted, or authorized by an individual to be the legally binding equivalent of the individual's handwritten signature.

Digital Signature: An electronic signature based upon cryptographic methods of originator authentication, computed by using a set of rules and a set of parameters such that the identity of the signer and the integrity of the data can be verified.

References:

ICH GCP E6 (R2), 9 November 2016. Note: This checklist will be revised after the final version of ICH E6(R3) has been disseminated. Please contact swissethics if you have questions on this regard.

Swiss Federal Law: Human Research Act (HRA), Humanforschungsgesetz (HFG; SR 810.30), loi relative à la recherche sur l'être humain (LRH; RS 810.30), legge sulla ricerca umana (LRUm; RS 810.30)

Guideline on computerised systems and electronic data in clinical trials, Good Clinical Practice Inspectors Working Group (GCP IWG), 9 March 2023, EMA/INS/GCP/112288/2023