

Electronic Informed Consent

Introduction

This document attempts to provide a general guideline, in form of a checklist, applicable to clinical trials (i.e. research projects that are subjected to the Clinical Trials Ordinance, ClinO) on the use of an electronic informed consent (eIC) to convey information related to the research project to potential study's subjects.

Currently, 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, while the subject's consent must still be documented on paper with a hand-written signature of both the patient and the investigator. That is electronic and/or digital signatures are not yet permitted. The legal validity of an electronic and/or digital signatures is at present under review and the scope of this document will be amended in case electronic and/or digital signatures are integrated in the eIC interview process.

It is recommended that the investigator, project leader, or the sponsor of the research project discuss plans for using an eIC with the Ethics Committee prior to finalizing the development of the eIC to ensure that the Ethics Committee agrees that the format may be used to convey the information the subjects.

The requestor must submit the same eIC materials to the Ethics Committee that will be presented to the subjects to obtain their consent for participation in the clinical investigation. 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, the requestor should provide the link to the Web page for downloading the App.

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, and card readers, etc.) to convey information related to the study and to obtain and document informed consent (FDA definition). In Switzerland an eIC makes use of electronic systems to convey the information related to the study only, while the subject's consent must be documented on paper with a hand-written 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 1.60.1).

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: means 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: Digital signature means 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.

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

Nr.	Points to be considered	Requirement (R)	in place	Reference (document, software, application, etc.)	comment
1	Computerized systems used for eIC				
1.1	When using electronic trial data handling and/or in case remote electronic trial data systems, the sponsor must comply with ICH-GCP 5.5.3.	R	Yes <input type="checkbox"/> / No <input type="checkbox"/>		
1.2	The computer programs/systems are validated in accordance with ICH GCP 1.65 for completeness, accuracy, reliability, consistent performance, and intended use.	R	Yes <input type="checkbox"/> / No <input type="checkbox"/>		
1.3	A system is in place to ensure data integrity throughout and after termination* of the research project, for example when making changes to the computerized systems, such as upgrades or migration of the data. *see also 4.3, 5.4	R	Yes <input type="checkbox"/> / No <input type="checkbox"/>		

2	eIC				
2.1	The content of the eIC complies with ICH-GCP 3.1.9. and 4.8.	R	Yes <input type="checkbox"/> / No <input type="checkbox"/>		
2.2	A process/system is in place to ensure that the eIC process is appropriate for subjects with impaired motor skills, poor eyesight, lack of familiarity with electronic devices, etc.	R	Yes <input type="checkbox"/> / No <input type="checkbox"/>		
2.3	If an <u>interactive</u> computer program is used, this is appropriate for the intended audience (subject's age, language, comprehension level)		Yes <input type="checkbox"/> / No <input type="checkbox"/>		
2.4	At the end of the eIC process, a paper-copy of the signed consent form is given to the subject. The signed original consent form must be filed in the investigator site file.	R	Yes <input type="checkbox"/> / No <input type="checkbox"/>		
3	Remote / on-site access				
3.1	The eIC material is accessible remotely and at the investigational site.	R	Yes <input type="checkbox"/> / No <input type="checkbox"/>		
3.2	A system is in place to ensure that the subject has the opportunity to ask questions and receive answers prior to signing the paper consent form to participate in the study, even if he/she accesses the eIC remotely	R	Yes <input type="checkbox"/> / No <input type="checkbox"/>		

4	Data protection, confidentiality and retention				
4.1	A validated system is in place to ensure subject's privacy, when electronic communication tools are used as part of the eIC interview process (ICH-GCP 2.11)	R	Yes <input type="checkbox"/> / No <input type="checkbox"/>		
4.2	A validated system is in place to ensure that the subject's data is stored securely when tools are used as part of the eIC interview process (ICH-GCP 2.11)	R	Yes <input type="checkbox"/> / No <input type="checkbox"/>		
4.3	<p>A system is in place to ensure that the original eIC and the <u>signed</u> paper consent form are archived appropriately and securely for 10 years* at study end and that it can be retrieved easily, if necessary (e.g. by archiving the operating system and applications).</p> <p>*15 years for research projects with medical devices</p>	R	Yes <input type="checkbox"/> / No <input type="checkbox"/>		

5	Amended eIC				
5.1	<p>A validated system to track changes to the eIC with audit trail capability.</p> <p>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</p>	R	Yes <input type="checkbox"/> / No <input type="checkbox"/>		
5.2	A system is in place to ensure that approved amendments to the eIC are timely transmitted to the subject.	R	Yes <input type="checkbox"/> / No <input type="checkbox"/>		
5.3	A process is in place to ensure the subject is given an adequate opportunity to ask questions about the amended content	R	Yes <input type="checkbox"/> / No <input type="checkbox"/>		
5.4	<p>A system is in place to ensure that the original <u>amended</u> eIC and the <u>signed</u> paper form of the amended IC version are archived appropriately for 10 years* at study end and that all amended versions can be retrieved easily, if necessary (e.g. by archiving the operating system and applications).</p> <p>*15 years for research projects with medical devices</p>	R	Yes <input type="checkbox"/> / No <input type="checkbox"/>		

6	Others				
6.1	The eIC is available as hard copy for review, audits, inspections	R	Yes <input type="checkbox"/> / No <input type="checkbox"/>		

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 subject understand the content of the IC 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 research project, 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 subject are not altered.

Place and Date:

Signature:

References:

ICH GCP E6 (R2), 9 November 2016

Guidance Use of electronic informed consent in clinical investigations, questions and answers. FDA, December 2016.

Guidance for Industry Computerized Systems Used in Clinical Investigations. FDA, May 2007.

Code of Federal Regulations, 21 CFR Part 11 – electronic records; electronic Signatures