HEALTH SCIENCES AUTHORITY

REGULATORY GUIDANCE

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CLINICAL TRIALS GUIDANCE

ELECTRONIC CONSENT

GN-IOCTB-14 Rev. No. 004

HSA
Health Sciences Authority

PREFACE

This document is intended to provide general guidance. Although we have tried to ensure that the information contained here is accurate, we do not, however, warrant its accuracy or completeness. The Health Sciences Authority (HSA) accepts no liability for any errors or omissions in this document, or for any action / decision taken or not taken as a result of using this document. If you need specific legal or professional advice, you should consult your own legal or other relevant professional advisers.

In the event of any contradiction between the contents of this document and any written law, the latter should take precedence.

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REVISION HISTORY

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GN-IOCTB-14 Rev. No. 001 (06 Nov 2020)

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SUMMARY OF KEY AMENDMENTS

- Aligned the background (Section 1.2) and general considerations for e-consent (Sections 2.1 to 2.5, 2.8 to 2.10, 2.12 to 2.14) with the ICH E6 (R3) Good Clinical Practice (GCP) guideline
- Clarified that electronic signatures for documenting informed consent (Section 2.10) should comply with the Electronic Transactions Act (ETA) and the ICH E6 (R3) GCP guideline. In general, you should ensure the following for an electronic signature:
  - A reliable method is used to identify the person who signed it and to indicate that person's intention for that purpose;
  - The electronic signature must be linked to the signed version of the informed consent record such that it cannot be altered; and
  - The date and time when the signature was applied is recorded (e.g., timestamp).

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1. INTRODUCTION

1.1. Purpose

The purpose of this document is to provide guidance to sponsors and investigators on electronic consent (i.e. e-consent).

Please note that references to participants in this guidance also apply to legal representatives of participants who are minors or adults lacking capacity.

1.2. Background

1.2.1. **Overview of informed consent requirements**

Informed consent is an integral feature of the ethical conduct of a clinical trial. Trial participation should be voluntary and based on an informed consent process that ensures participants (or their legal representatives, where applicable) are well-informed.

The ICH[1] E6 (R3) Good Clinical Practice (GCP) guideline defines informed consent as a process by which a participant or their legal representative voluntarily confirms their willingness to participate in a clinical trial after having been informed and been provided with the opportunity to discuss all aspects of the clinical trial that are relevant to the participant's decision to participate.

Freely given informed consent should be obtained and documented from every participant or their legal representative prior to clinical trial participation. The investigator is responsible for obtaining informed consent from the participant prior to clinical trial participation. The process and information provided should be designed to achieve the primary objective of enabling participants to evaluate the benefits, risks and burden of participating in the trial and to make an informed decision on whether or not to participate in the trial. The information

[1] International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use

provided during the informed consent process should be clear and concise so as to be understandable by potential participants or their legal representative.

The informed consent process often continues beyond obtaining the participant's initial consent at the time of enrollment, and may involve providing new information as the clinical trial progresses.

1.2.2. **Electronic consent (e-consent)**

Varied approaches to the provision of information and discussion about the trial may be used during the informed consent process. Informed consent is documented by means of a written (paper or electronic), signed and dated informed consent form.

For the purpose of this guideline, e-consent refers to the use of computerised systems that may employ any digital media (e.g., text, images, videos and other interactive methods) to:

(i) convey information related to the clinical trial; and/or

(ii) to document informed consent, via electronic signature, using an electronic device such as a smartphone, tablet or computer.

For example, it would be possible for the participant to sign the informed consent form on a paper-based form following provision of the information electronically, or the provision of information and documentation of informed consent could be entirely electronic.

E-consent may be used to supplement or replace paper-based informed consent processes. However, it is important to note that e-consent should not replace the informed consent discussion between the investigator and the participant. The method of obtaining an informed consent should ensure the broadest possible access to clinical trials. Alternative methods for provision of information and documentation of informed consent should be available for those unable or unwilling to use electronic means.

E-consent offers a number of potential benefits, including:

(i) Improved participant engagement and understanding, as varied approaches like text, images, videos and other interactive methods may be incorporated in the e-consent system;

(ii) Increased accessibility and convenience, as e-consent may be used as a decentralised element in the clinical trial for obtaining informed consent remotely;

(iii) Increasing work efficiencies for sponsors and investigators, through standardised delivery of approved informed consent materials to all investigator sites, and quick dissemination of revised informed consent materials, where applicable;

(iv) Improving quality through version control, audit trails and reduced non-compliances; and

(v) Complementing risk-based monitoring through centralised monitoring and remote monitoring of informed consent processes etc.

Conversely, e-consent may pose certain challenges, including:

(i) Increased costs, resources and time required to set up and maintain the e-consent system;

(ii) Unfamiliarity and lack of experience of investigators and institutions in using the e-consent system;

(iii) Reluctance or difficulty in navigating or using computerised systems due to reduced digital literacy, poor eyesight or impaired motor skills in some trial populations or unavailability of stable internet access;

(iv) Possible incompatibilities with institutional policies for data protection; and

(v) Needing to develop business continuity plans in the event of system failure or maintenance.

Regardless of the mode of informed consent implemented for clinical trials, sponsors and investigators should ensure the following:

(i) Rights, safety, well-being and privacy of participants are safeguarded;

(ii) Data integrity[2] and confidentiality are assured;

(iii) Basic principles of informed consent (i.e. information, comprehension and voluntariness) are assured;

(iv) Regulatory provisions for informed consent as specified in the applicable clinical trials regulations and ICH E6 (R3) GCP guideline are complied with.

1.3. Scope

This guidance applies to clinical trials regulated by HSA, namely:

(i) Clinical trials of Therapeutic Products[3] and Class 2 Cell, Tissue and Gene Therapy Products (CTGTPs)[4] that are subject to the requirements for a Clinical Trial Authorisation (CTA) or a Clinical Trial Notification (CTN);

(ii) Clinical trials of Medicinal Products[5] that are subject to the requirements of a Clinical Trial Certificate (CTC).

[2] Data integrity includes the degree to which data fulfil key criteria of being attributable, legible, contemporaneous, original, accurate, complete, secure and reliable such that data are fit for purpose.

[3] Therapeutic Product and CTGTP are defined in the First Schedule to the Health Products Act.

[4] Class 1 and Class 2 CTGTP are defined in the Health Products (Cell, Tissue and Gene Therapy Products) Regulations.

- Class 1 CTGTP means a CTGTP that —
  (a) is the result of only minimal manipulation of human cell or tissue;
  (b) is intended for homologous use;
  (c) is not combined or used with a therapeutic product or a medical device; and
  (d) is assigned by HSA as a Class 1 CTGTP due to a lower health risk to a user of the product.
- Class 2 CTGTP means a CTGTP other than a Class 1 CTGTP.

[5] Medicinal Product is defined in the Medicines Act.

2. GENERAL CONSIDERATIONS FOR E-CONSENT

2.1. What are the regulatory requirements for e-consent?

2.1.1. Sponsors and investigators must comply with the regulatory requirements for informed consent, as specified in the applicable clinical trials regulations and ICH E6 (R3) GCP guideline.

2.1.2. Additionally, sponsors and investigators must comply with the Personal Data Protection Act (PDPA) for regulatory requirements on the collection, use and disclosure of personal data; and the Electronic Transactions Act (ETA) for regulatory requirements on the use of electronic signatures.

2.2. What are the data governance requirements for the e-consent system, based on ICH E6 (R3) GCP guideline?

2.2.1. Please refer to our Regulatory Guidance on Use of Computerised Systems in Clinical Trials for the data governance requirements for e-consent systems. In general, the e-consent system should be fit for purpose and factors critical to their quality should be addressed in their design and adaptation for clinical trial purposes to ensure the integrity of the relevant trial data.

2.3. Is IRB approval required for the e-consent system?

2.3.1. The investigator should have the IRB’s documented approval / favourable opinion of the informed consent materials and process prior to consenting and enrolling participants. Please consult your IRB for the required information to be submitted for the e-consent system.

2.4. Is HSA approval required for the e-consent system?

2.4.1. HSA approval is not required for the e-consent system. However, sponsors and investigators should describe the proposed e-consent system in their clinical trial application to HSA, and may consult with HSA prior to implementation as necessary.

2.4.2. It is recommended that the following be submitted to HSA in the clinical trial application, where applicable:

(i) E-consent materials;
(ii) Screen shots and/or mock ups of the e-consent system;
(iii) Proposed e-consent process;
(iv) Authentication and identity verification process;
(v) Methods for electronic signatures; and
(vi) Measures in place to safeguard participant privacy, and data integrity and confidentiality.

2.4.3. Sponsors and investigators should notify HSA of subsequent changes to the e-consent system that may significantly impact participant privacy, or data integrity or confidentiality of the e-consent data. Such changes should be submitted to HSA as substantial amendment applications.

2.5. What information should be provided in the e-ICF?

2.5.1. Sponsors and investigators must ensure that the electronic informed consent form (e-ICF) contains all the elements of an informed consent form, as specified in the applicable clinical trials regulations and ICH E6 (R3) GCP guideline.

2.5.2. The characteristics of the potential trial population (e.g., participants may lack familiarity with computerised systems) and the suitability of the method of obtaining consent should be taken into consideration when developing the informed consent materials and process. When

computerised systems are used to obtain informed consent, participants may be given the option to use a paper-based approach as an alternative.

2.5.3. The information should be as clear and concise as possible, use simple language and avoid unnecessary volume and complexity. This is to ensure that the participants have an adequate understanding of the objectives of the trial, alternative treatments, potential benefits and risks, burdens, their rights and what is expected of the participants to be able to make an informed decision as to their participation in the trial.

2.5.4. None of the information provided to the participant during the informed consent process should contain any language that causes the participant to waive or to appear to waive any legal rights, or that releases or appears to release the investigator, the institution, the sponsor or their service providers from liability for negligence.

2.6. How can the participant's understanding of the information presented in the e-ICF be enhanced, assessed and reinforced?

2.6.1. Sponsors and investigators may use the following interactive tools to enhance, assess and reinforce the participant's understanding of the e-ICF:

(i) Section views to allow content to be viewed in separate sections;

(ii) Digital media such as texts, images, videos and other interactive methods etc.;

(iii) Glossaries to provide definitions to certain terminologies;

(iv) Call out boxes to reinforce key ideas in 1-2 sentences;

(v) Flags for participants to identify sections that require further clarifications;

(vi) Comment boxes for participants to document questions;

(vii) Self-assessment checklists or short questions about the clinical trial to assess participant's understanding of the information presented; and/or

(viii) Section-based attestation to allow participants to acknowledge understanding of specific sections.

2.6.2. Regardless of the interactive tools used, the communication between the investigator and the potential participant is often the most effective way of improving potential participants' understanding of what is involved.

2.7. Who is responsible for obtaining e-consent?

2.7.1. The investigator, who is delegated by the Principal Investigator and qualified to obtain informed consent, is responsible for obtaining e-consent from the participant. They should conduct the informed consent discussion with the participant prior to signing the e-ICF.

2.8. Where should e-consent be obtained?

2.8.1. The e-consent may be obtained either:

(i) In-person at the investigator site; or

(ii) Remotely via video conferencing, where the investigator and participant are at different locations (i.e. remote consent). Refer to Section 2.13 for additional information on remote consent.

2.9. How should the informed consent discussion be conducted?

2.9.1. The purpose of the informed consent discussion is to ensure that the investigator has provided adequate information about the clinical trial to the participant for the participant to understand and voluntarily make an informed decision about clinical trial participation. Simply providing a potential participant with this information (whether by paper or electronic

means) would not be adequate as the informed consent discussion requires a two-way communication in real time between the investigator and the participant.

2.9.2. The investigator site staff should be trained on navigating the e-consent system. Training records should be maintained on file. Similarly, participants should be trained or given written instructions on navigating the e-consent system.

2.9.3. Sponsors and investigators should ensure that the correct version of the e-ICF that has been approved by the IRB and HSA (where applicable) has been uploaded into the e-consent system.

2.9.4. The investigator should conduct the informed consent discussion in a conducive environment, respecting the privacy of the participant and confidentiality of the information being discussed. There should be no coercion or undue influence.

2.9.5. The investigator should assure themselves of the identity of the participant. This may be performed via verification of a photo ID of the participant.

2.9.6. An impartial witness should participate in the informed consent discussion if the participant is unable to read or sign/date the informed consent form.

2.9.7. A translator should participate in the informed consent discussion if the participant is unable to communicate with the investigator in the same language.

2.9.8. The participant should be given ample time and opportunity to ask questions about the clinical trial to decide on clinical trial participation. All questions should be answered in a satisfactory manner.

2.10. How should e-consent be documented?

2.10.1. Prior to trial participation, the participant and the investigator who conducted the informed consent discussion should sign and date the informed consent form. By signing the informed consent form, the investigator attests that the informed consent was freely given by the participant and the consent information was accurately explained to and apparently understood by the participant. The informed consent process may involve a physical or an electronic signature and date.

2.10.2. In situations where information relating to the clinical trial is conveyed using computerised systems, and the informed consent form is signed via a physical signature and date, all relevant parties should sign and date the hard copy of the informed consent form. The investigator site team may then upload the copy of the signed informed consent form in the e-consent system, as required.

2.10.3. In situations where information relating to the clinical trial is conveyed using computerised systems, and the consent is documented electronically, the electronic signature should be a unique mark, symbol or entry executed, adopted or authorised by an individual that:

(i) Meets the requirements of an electronic signature in accordance with the Electronic Transactions Act (ETA).

(ii) Shows expression of will; and

(iii) Allows authentication of the signatory (i.e., establish a high degree of certainty that a record was signed by the claimed signatory).

2.10.3.1. In general, you should ensure the following for an electronic signature:

(i) A reliable method is used to identify the person who signed it and to indicate that person’s intention for that purpose;

(ii) The electronic signature must be linked to the signed version of the informed consent record such that it cannot be altered; and

(iii) The date and time when the signature was applied is recorded (e.g., timestamp).

2.10.3.2. Please note that it is not recommended to copy and paste a physical signature onto the e-ICF.

2.10.4. The investigator should document the e-consent process in the participant's source records. Information on the protocol reference, informed consent date, informed consent process and provision of a signed copy of the informed consent form should be documented.

2.11. How should a copy of the e-ICF be provided?

2.11.1. The participant should receive a signed copy of the e-ICF.

2.11.2. The investigator may provide a soft copy or hard copy of the signed e-ICF to the participant.

2.11.2.1. If a soft copy of the signed e-ICF is provided to the participant, the investigator should consider sending it in a file format that allows secure and limited access and prevents unauthorised editing of the signed e-ICF.

2.11.2.2. If a hard copy of the signed e-ICF is provided to the participant, all informed consent materials used during the informed consent discussion should be provided to the participant for reference.

2.12. What should be done when new information becomes available?

2.12.1. When new information becomes available during the clinical trial,

(i) The participant or their legal representative should be informed in a timely manner if new information becomes available that may be relevant to the participant's willingness to continue trial participation. The communication of this information and confirmation of the willingness to continue trial participation should be documented.

(ii) The new information that could impact a participant's willingness to continue participation should be assessed to determine if re-consent is needed (e.g., depending on the stage of the trial, consideration should be given to whether the new information is relevant only to new participants or to existing participants). If re-consent is needed (e.g., information on emerging safety concerns), new information should be clearly identified in the revised informed consent materials. Revised informed consent materials should receive the IRB approval / favourable opinion in advance of use.

2.12.2. Sponsors and investigators may have the flexibility to use paper and electronic consent methods independently or in combination throughout the clinical trial.

2.13. What are additional considerations if e-consent is conducted remotely via video conferencing (i.e. remote consent)?

2.13.1. Investigators may consider the following if e-consent is conducted remotely, where applicable:

(i) Consult the institution (e.g. IT department) on the acceptable telemedicine software to be used for remote consent;

(ii) Ensure that the informed consent discussion is conducted in a secure manner, and adequate measures are in place to safeguard participant privacy and data integrity and confidentiality;

(iii) Provide a copy of the ICF (e-ICF/ hardcopy ICF) to the participant to read before the informed consent discussion;

(iv) Verify the identity of the participant during the remote consent discussion (e.g., by verifying a photo ID);

(v) Ensure that all parties sign and date the e-ICF;

(vi) Document details of the remote consent process in the participant's source records;

(vii) Retain the signed copy of the e-ICF (signed by all parties) at the investigator site in a manner that has secure and limited access and prevents unauthorised editing. The participant should also be provided a signed copy of the e-ICF in a similar manner.

2.13.2. If e-consent is used remotely for enrollment of new participants, an impartial witness should participate in the informed consent discussion regardless of whether the participant is unable to read or sign/date the ICF. The role of the impartial witness in this case would be to ensure that the identity of the potential participant has been verified and consent has been freely given.

2.14. What are the additional considerations for privacy and data protection?

2.14.1. Prior to implementation, investigators should consult their institutions (e.g. IT department) to ensure that the e-consent system is in line with institutional policies for data protection and electronic signatures.

2.14.2. Sponsors and investigators should ensure that e-consent system has secure and limited access and audit trail.

2.14.3. The personal data of the trial participant (e.g. name and email address of the participant) should be encrypted within the e-consent system. A reasonable and appropriately equivalent measure may be utilised if encryption is not possible. The sponsor and any third party should not have access to the personal data of the trial participant throughout the clinical trial and even after study completion.

2.14.4. In situations where the trial participant is required to create an account to access the e-consent system, the investigator should ensure that the personal data of the participant (e.g. name and email address) is not provided to the sponsor or other third parties due to privacy and confidentiality concerns.

2.14.5. Direct access to the e-consent system should be provided during monitoring, audits and GCP inspections.

2.15. What are the additional considerations for monitoring an e-consent system?

2.15.1. Sponsors are responsible for monitoring the e-consent system. This may include site monitoring (performed on-site or remotely) or centralised monitoring.

2.15.2. Sponsors and investigators should ensure the following for monitoring of the e-consent system:

(i) Build protection against potential issues that may lead to breach of privacy and confidentiality;

(ii) Identify areas of training and best security practices; and

(iii) Consider restricting access to data fields that may identify participants for remote monitoring or centralised monitoring.

2.15.3. Access to the personal data of the participant during centralised monitoring or remote monitoring should be disabled. As it will not be

possible to verify the identity of the participant through remote monitoring or centralised monitoring, sponsors should ensure that Monitors verify the identities of the participants during on-site monitoring visits.

3. REFERENCES

(i) Health Products (Clinical Trials) Regulations
(ii) Medicines (Clinical Trials) Regulations
(iii) Personal Data Protection Act (PDPA)
(iv) Electronic Transactions Act (ETA)
(v) ICH E6 (R3) Good Clinical Practice (GCP) Guideline
(vi) Regulatory Guidance on Use of Computerised Systems in Clinical Trials
(vii) FDA Guidance on Use of Electronic Consent, Questions and Answers, Guidance for Institutional Review Boards, Investigators, and Sponsors - Dec 2016
(viii) EMA Guideline on Computerised Systems and Electronic Data in Clinical Trials - 9 Mar 2023

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