ELECTRONIC METHODS FOR SEEKING INFORMED CONSENT

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1 INTRODUCTION

1.1 The Academic & Clinical Central Office for Research & Development (ACCORD) is a joint office comprising clinical research management staff from NHS Lothian (NHSL) and the University of Edinburgh (UoE).

1.2 The Health Research Authority (HRA) and Medicines and Healthcare products Regulatory Agency (MHRA) published a Joint Statement on Seeking Consent by Electronic Methods, September 2018.

1.3 Electronic methods for seeking, confirming and documenting informed consent (often referred to as e-consent) is an acceptable approach enabling participants to be provided with information via digital multimedia (e.g. on a tablet) or allowing their informed consent to be documented via electronic signature. This approach can supplement a traditional paper-based method or where appropriate, replace it.

1.4 The MHRA GxP Data Integrity Guidelines and Definitions (Revision 1 March 2018) define an electronic signature as: '*A signature in digital form (bio-metric or non-biometric) that represents the signatory. This should be equivalent in legal terms to the handwritten signature of the signatory.'* Electronic signatures may be classified as;

- Simple; finger drawn signature, typed name, finger print scan.
- Advanced; uniquely linked to the signatory to allow for identification of the signatory.
- Qualified; an advanced electronic signature that is created by a qualified electronic signature creation device and based on a qualified certificate for electronic signatures.

1.5 The type of electronic signature used to document the consent process will be risk-based and proportionate to the nature and complexity of the research. Consideration should be given to:

- How the signature is attributable to an individual.
- How the act of 'signing' is recorded within the system so that it cannot be altered or manipulated without invalidating the signature or status of the entry.
- How the record of the signature will be associated with the entry made and how this can be verified with a full GxP audit trail.

- The security of the electronic signature i.e. so that it can only be applied by the 'owner' of that signature.

1.6 Regardless of whether paper-based or multimedia formats are used, the process of obtaining voluntary and informed consent must be upheld in accordance with the principles of Good Clinical Practice (GCP) and regulatory requirements.

2 SCOPE

2.1 This policy is applicable to researchers and support staff seeking, confirming and documenting e-consent for studies sponsored by NHSL / UoE.

3 POLICY

3.1 Implementation of e-Consent in Regulated or Complex Research Studies

3.1.1 For studies subject to a combined risk assessment (GS002) electronic methods for seeking informed consent will be documented in the study protocol and appraised at the study risk assessment. Appropriate risk mitigation factors will be implemented by the Sponsor(s), this may include the development of a QA strategy (e.g. application of a computer system validation review for an e-signature / audit of process) and / or Monitoring strategy (e.g. increased monitoring frequency of the consent process).

3.1.2 For type A studies where the trial involves risks no higher than that of standard medical care, then a simple e-signature involving the participant tracing their handwritten signature using a finger or stylus or biometric e-signatures can be used (this may also include typewritten or scanned e-signatures). Regardless of the use of a simple e-signature, verification of the participant's identity should still be confirmed following section 2.4.

3.1.3 For type B & type C studies (including Phase I studies) where the trial involves higher risk than that of standard medical care, simple e-signatures (e.g. finger drawn stylus or biometric e-signature) can be used however a typewritten or scanned image of handwritten signatures should not be used. Verification of the participant's identity should be no more burdensome than it would normally be for the traditional consent process. Where the participant is not known to the research team, there should be an auditable trail to demonstrate trust of the identity of the signatory.

3.1.4 Where consent is given remotely the Investigator should ensure the e-consent process allows for discussion and ample opportunity to ask questions, this can be accomplished for example via phone calls or secure video conferencing. If the participant is required at some point to visit a study site for the purposes of the trial then verification can be done in person using

information from official photo ID provided this is done prior to receiving the intervention. If clinical trial activities are solely conducted remotely, it may not be possible to verify who the participant is therefore an advanced or qualified e-signature should be used.

3.1.5 Where the participant has capacity but is uncomfortable with technology and therefore unable to indicate their consent by signing (either by wet-ink / electronic signature or marking a document) then their consent may be given orally in the presence of at least one independent witness and recorded in writing.

3.2 Implementation of e-Consent in Other Research Studies

3.2.1 Electronic methods for seeking informed consent will be documented in the study protocol and agreed by the Sponsor(s).

3.2.2 For research studies involving minimal risk (e.g. surveys or non-sensitive qualitative research), then any simple e-signature can be used including typewritten or scanned e-signature.

3.2.3 For postal/online surveys or self-administered questionnaire-based research where identifiable personal data are collected, then the participant must be able to actively signify their consent e.g. by providing an explicit consent statement and a tickbox within the questionnaire. A handwritten or biometric eSignature is not required.

3.2.4 Where the research study involves more than minimal risk or burden, simple e-signatures that involve the participant tracing their handwritten signature using a finger or a stylus or biometric e-signatures should be considered as these allow for direct comparison with e-signatures and/or wet-ink signatures previously used by the participant.

3.3 Things to Consider

- NHS Lothian provides the NHS Scotland approved digital communications tool NHS Near Me. This is a platform providing secure online consultation with patients and should be used when communicating with patients via video. Request Forms, Guides and Information on using NHS Near Me can be found on the NHS Lothian Intranet.
- Non-editable PDF copies of Participant Information Sheet (PIS) / Informed Consent Forms (ICF) should always be provided. It should be possible to verify which version the PIS/ICF the e-signature applies to.
- Source documentation, including audit trails and metadata should be available in the Investigator Site File (ISF).
- Personal identifiable data should not be disclosed beyond the site unless explicit agreement has been sought from the Sponsor(s). General Data Protection Regulation (GDPR) and local policies should be followed.

When transferring identifiable data an NHS.net account should be used. Approval may be required from NHS Lothian Information Governance.

- A copy of the informed consent documentation needs to be provided to the participant.
- Access to the e-consent system should be readily available to auditors, inspectors and monitors both during and end of the trial.
- To aid potential participants understanding of the information presented, interactive questions could be included in the consent process.
- Examples of advanced e-signature software includes AdobeSign and DocuSign.

4 REFERENCES AND RELATED DOCUMENTS

- Joint Statement on Seeking Consent by Electronic Methods (September 2018).
- The MHRA GxP Data Integrity Guidelines and Definitions (Revision 1, March 2018).
- ICH-GCP E6(R2): Guideline for Good Clinical Practice
- SOP GS002 Combined Risk Assessment

5 DOCUMENT HISTORY

Version Number	Effective Date	Reason for Change
1.0	20-Jul-20	New Policy

6 APPROVALS

Sign	Date
 AUTHOR: Lorn Mackenzie, QA Manager, NHSL, ACCORD	Jul 2, 2020
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