University College London Hospitals
NHS Foundation Trust

UCLH/UCL Joint Research Office

Electronic Methods for Seeking Informed Consent

Notes from the "Joint Statement on Seeking Consent by Electronic Methods" by MHRA & HRA, September 2018:
https://www.hra.nhs.uk/about-us/news-updates/hra-and-mhra-publish-joint-statement-seeking-and-documenting-consent-using-electronic-methods-econsent/

eConsent: The use of any electronic media e.g. graphics, audio, website etc to convey information related to the study and to document informed consent via an electronic device e.g. smartphone or computer.

Overview:

- It is acceptable to use online text or multimedia as the main method of informing participants, but this may unintentionally discriminate against people who cannot use such technology. Alternative methods should be available for those unwilling or unable to use electronic methods.
- 3 groups of electronic signatures:
    - *Simple electronic signatures* – Finger drawn signature, typed name or fingerprint scan
    - *Advanced electronic signatures* – Uniquely linked to the signatory and allows identification of the signatory
    - *Qualified electronic signatures* – An advanced electronic signature that is created by a qualified electronic signature creation device and based on a qualified certificate for electronic signatures

Legal Requirements for Seeking Consent in CTIMPs: The methods used to inform and document the consent of participants need to comply with the requirements of The Medicines for Human Use (Clinical Trials) Regulations 2004, thus implementing the EU Clinical Trials Directive (2001/20/EC) in UK law.

- Participants must be provided with information on the nature, significance and risks of the trial and the right to withdraw from the trial at any time. A contact point must also be provided.
- An interactive interview between the investigator or a member of the investigating team and the participant must be conducted to provide the participant with the opportunity to understand the nature, significance and risks of the trial to facilitate informed decision making.
- The interview should be conducted in person where possible or via a two-way communication method e.g. telephone or video conferencing if approved by a Research Ethics Committee. The communication method must be secure and confidentiality must be maintained. Whichever method is utilised, it should allow for confirmation of the participant's identity, particularly where the interview and documentation of consent is carried out by electronic methods at a distance.

- Where a hard copy of the trial information is provided via an eConsent system, it must contain sufficient information regarding the nature, significance and risks of the trial and the participant's right to withdraw from the trial at any time.

Best Practices for Seeking Consent in CTIMPs:

- Type A studies (the CTIMP involves risks no higher than that of standard medical care): Simple eSignatures involving the participant tracing their handwritten signature using a finger or stylus or biometric eSignatures should normally be used.
- Type B & Type C studies (higher risk than that of standard medical care): Typewritten or scanned images of handwritten signatures should not normally be used. Where consent is given remotely and 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.

Best Practices for Seeking Consent in non- CTIMPs:

- Any simple electronic signature is normally adequate for the majority of non-CTIMP research involving only negligible or minimal risk.
- Where the research involves more than minimal risk or burden, simple eSignatures that involve the participant tracing their handwritten signature using a finger or a stylus or biometric eSignatures should be considered as these allow for direct comparison with eSignatures and/or wet-ink signatures previously used by the participant.
- 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.

Important Points to Consider:

- Can the signature be dated, manually by the participant, or automatically by the eConsent system?
- Is it possible to verify which version of the PIS and consent form the electronic signature applies to?
- For interventional studies, are there methods in place to ensure that the person signing the electronic consent form is the person who will be participating in the study?