Seeking consent by electronic methods

Health Research Authority

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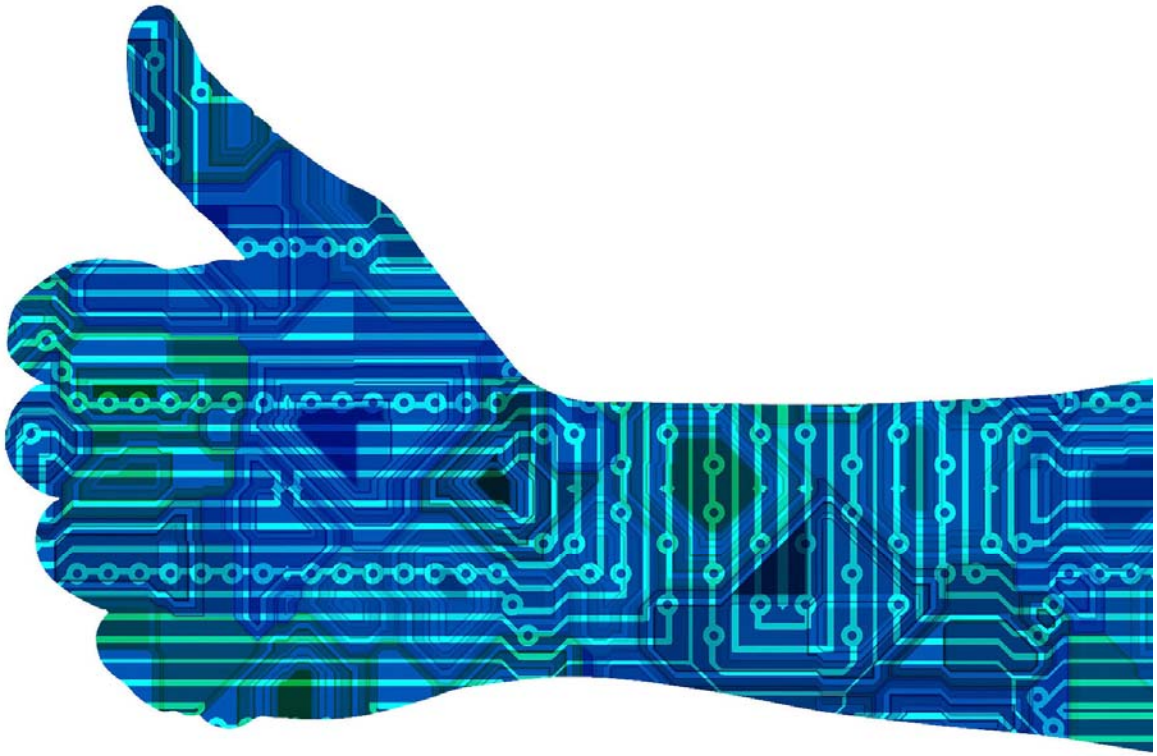

HRA/MHRA Joint statement on seeking consent by electronic methods

Joint policy position with MHRA: sets out the legal and ethical requirements for seeking and documenting consent using electronic methods.

Will be supplemented by guidance

'eConsent' = The use of electronic media (text, graphics, audio, video, podcasts; websites etc.) via an electronic device to

- **provide information related to the study** and/or
- **document informed consent (eSignatures)**

Electronic methods may be used for seeking, confirming and documenting informed consent in research studies (including eSignatures).

What is eConsent?

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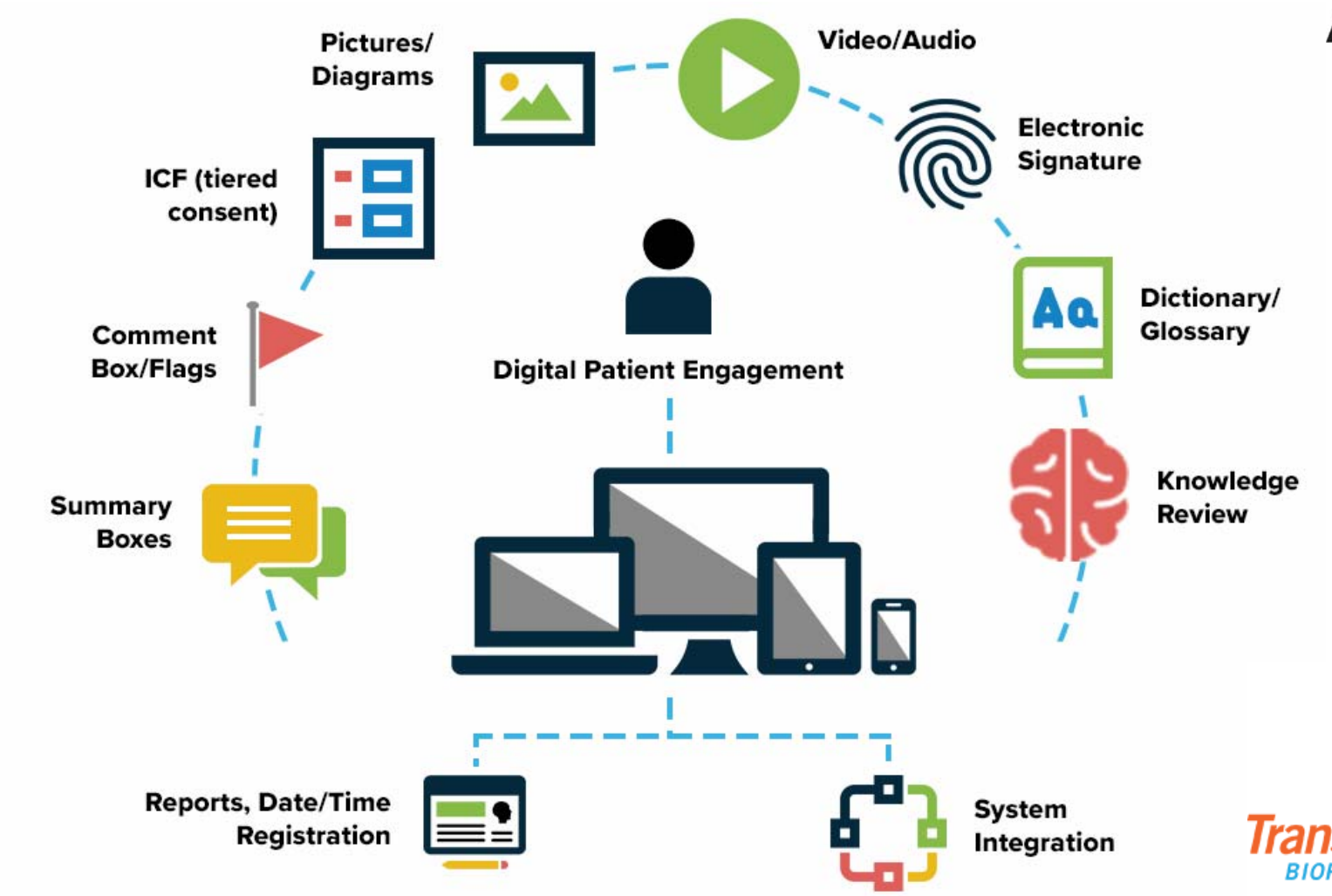

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Why use eConsent?

- Evidence that multimedia information preferred by potential participants
- Test and reinforce participant comprehension
- Improve understanding
- Self-assessment questions at key points - highlight areas of uncertainty
- Provides feedback on how materials could be improved

- Improve patient recruitment process and reduce dropout rates
- Enables process efficiencies

NB eConsent may not suit everybody - unintentionally discriminate against people not comfortable with or who cannot use technology

Does NOT replace face-to-face discussion between researcher and the participant

Legal Requirements - Drug trials:

Medicines for Human Use (Clinical Trials) Regulations 2004

What information must be provided?

Information on the **nature, significance, implications and risks** of the trial

Doesn't need to be in writing.

How?

Prior interview with the investigator or a member of the investigating team

- In person preferable
- Where justified: electronic methods that allow for two-way communication in real time (telephone, video conferencing or VoIP telephony etc). Important that confidentiality is maintained and method is secure

Legal Requirements - Drug trials:

Medicines for Human Use (Clinical Trials) Regulations 2004

How must consent be recorded?

In writing. Dated and signed, or otherwise marked by the participant

- ‘writing’ = ‘typing, printing, lithography, photography and other modes of representing or reproducing words in a visible form’.

- The Clinical Trials Regulations specifically allow use of electronic signatures for signing documents referred to in the Regulations.

- However, the type of electronic signature that should be used will depend upon the specific context of the trial.

Electronic signatures

What is an electronic signature?

The ‘eIDAS’ Regulation (EU) No 910/2014

Electronic signature = ‘data in electronic form which is attached to or logically associated with other electronic data and which is used by the signatory to sign’

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Types of electronic signature:

Simple

stylus or finger drawn signature, a typed name, a tick box and declaration, fingerprint scan (biometric)

Advanced

- uniquely linked to the signatory
- can identify the signatory
- signatory retains control
- linked to data within the signature that can detect changes

Qualified

As above PLUS created by *qualified electronic signature creation device* based on a *qualified digital certificate* for electronic signatures.

NB: Advanced/Qualified eSignatures may place disproportionate burden on researcher/participant and may not be appropriate

What type of electronic signature should I use?

Taking a proportionate approach do your recruitment and consent procedures taken as a whole mean that you can trust:

- **that the person who signed is who they say they are**
- **that the consent form they signed hasn't been altered**
- **when the signature was applied**, and

- **demonstrate that trust is justified if required?**

Answer will help decide whether a simple electronic signature may be used and, if so, what type.

Only in rare cases will an advanced or qualified eSignature be suitable.

What type of electronic signature should I use?

CTIMPs

“Type A” (risks *no higher* than that of standard medical care)

- **Any simple electronic signature** (including typewritten or scanned signatures)

“Type B” (risks *somewhat higher* than standard medical care) and
“Type C” (risks *markedly higher* than standard medical care (including Phase I)

- **Finger or stylus “handwritten” eSignatures or biometric eSignatures**

Allow direct comparison with eSignatures and/or wet-ink signatures previously used (Not typewritten or scanned images of handwritten signatures)

What type of electronic signature should I use?

CTIMP where the patient is remote at the time of consent

Where participant's identity can be verified using official photo ID via video link (or at general practices or other NHS sites local to the participant):

- **Finger or stylus "handwritten" eSignatures or biometric eSignatures**

Where not possible to confidently verify identity:

- **Advanced or qualified electronic signature may be preferable** (though not legally required)

Next Steps

- **Publish joint statement (June 2018)**
- **HRA: eConsent submission guidance for applicants (Summer/Autumn 2018)**
- **HRA: Update online guidance for researchers and ethics committees ‘Consent and Participant Information Sheet Preparation Guidance’ to incorporate eConsent (Summer/Autumn 2018)**

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Thank You

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