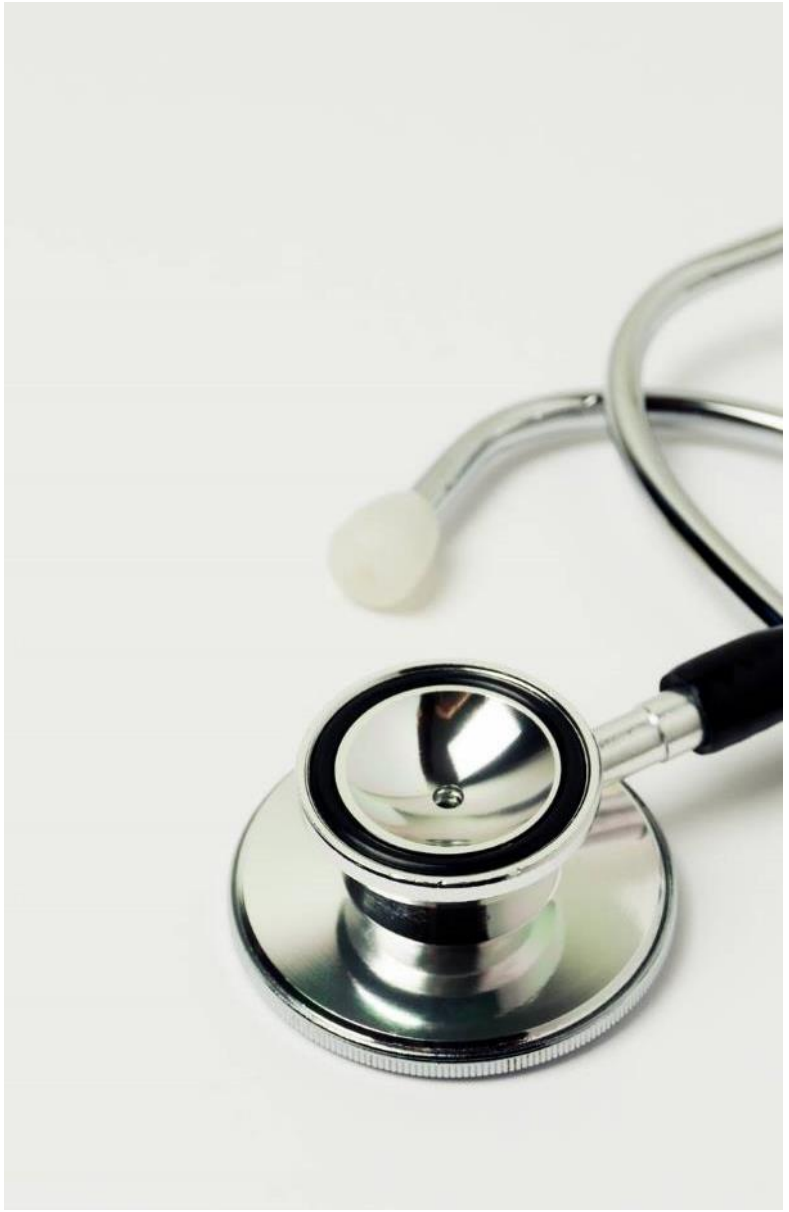
EXISTING GUIDANCE ON ECONSENT

Matt Hammond, Norwich CTU

WHO IS THIS AIMED AT

- First time users of eConsent
- Trial Managers, Data Managers and early career researchers

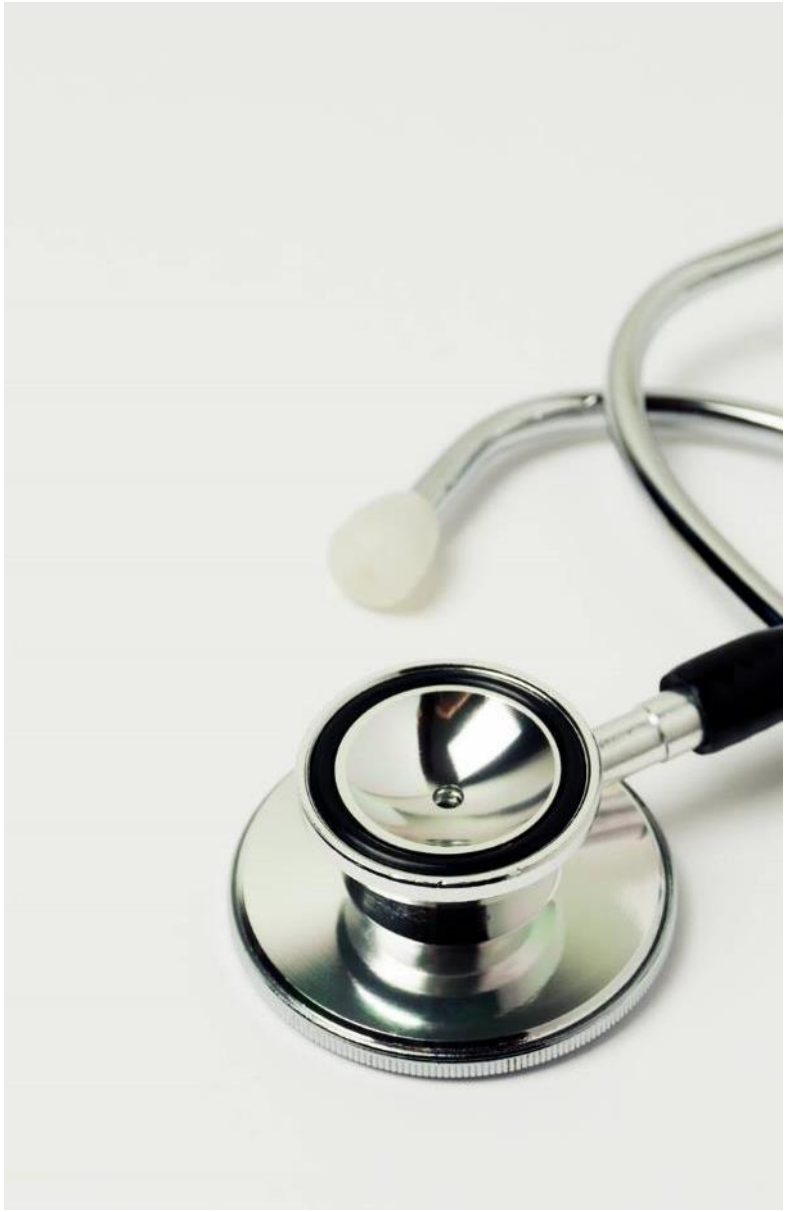


WHAT THIS TALK WILL COVER

- What is eConsent?
- What is the current guidance on the use of eConsent?
- What are eSignatures?
- Why you should use eConsent for your study
- Considerations when using eConsent

WHAT THIS TALK WON'T COVER

- Implementing eConsent in RedCAP (that's next week)



WHAT IS ECONSENT?

MHRA definition of eConsent

*"The use of **any electronic media** (such as text, graphics, audio, video, podcasts or websites) to **convey information** related to the study and to seek and/or **document informed consent** via an electronic device such as a smartphone, tablet or computer".*

WHAT IS ECONSENT?

- eConsent permits potential research participants to be **provided with the information** they need to make a decision via a tablet, smartphone or digital multimedia.
- It also enables informed **consent to be documented** using electronic signatures.
- eConsent ≠ Remote Consent
  - eConsent can still be performed 'on-site'.
- There is not one model for eConsent – it can be entirely remote, be used to enhance / supplement traditional on-site consent or be something in between.
- The model you decide to use should be determined by an assessment of the risks of the study and the population you wish to consent.

WHAT IS ECONSENT?

Informing and Educating the participant

- Can use video, infographics, audio, web-pages, graphics, podcasts to convey information on the study
- Highly configurable for the participant, can be interactive
- Delivered via a supplied tablet / smartphone or the participants own device.
- Information can be centrally controlled
- Knowledge Review can be performed if appropriate

+

Documenting Consent from the participant

- Consent captured by online electronic consent forms
- Use of eSignatures

All materials and the method of informed consent must be ethically approved

CURRENT GUIDANCE ON THE USE OF ECONSENT

MHRA AND HRA JOINT GUIDANCE ON ECONSENT (2018)

https://www.hra.nhs.uk/about-us/news-updates/hra-and-mhra-publish-joint-statement-seeking-and-documenting-consent-using-electronic-methods-econsent/

- Guidance produced primarily for clinical trials of investigational medical products (CTIMPs) but should be applied to all research conducted within the UK.
- Provided legal and ethical requirements for seeking and documenting eConsent
- Provided classifications and guidance on the use of **electronic signatures**.

MHRA

NHS SCOTLAND

Health and Social Care

NHS Health Research Authority

Joint statement on seeking consent by electronic methods

September 2018

The Health Research Authority is a Non-Departmental Public Body established to promote and protect the interests of patients in health research and to streamline the regulation of research. www.hra.nhs.uk

The Medicines and Healthcare products Regulatory Agency is an executive agency of the Department of Health and is the UK's regulator of medicines, medical devices and blood components for transfusion. www.gov.uk/government/organisations/medicines-and-healthcare-products-regulatory-agency

ECONSENT FOR CLINICAL TRIALS OF INVESTIGATIONAL MEDICINAL PRODUCTS

eConsent for CTIMPs has stricter requirements than for other forms of research.

- A discussion, in real time, **must** occur between the participant (or proxy consent giver) and the investigator or delegated team member in which the participant can ask questions and receive answers
- This interview can either be undertaken **in person or virtually**, via video call software such as MS Teams or AttendAnywhere.
- During this interview the participant must be informed of the **nature, significance, implications and risks of the trial** so that they can make an **informed decision** about whether to take part or not
- The interview can also be used to **confirm the participant's identity.**

ECONSENT FOR CLINICAL TRIALS OF INVESTIGATIONAL MEDICINAL PRODUCTS

- Following this discussion, informed consent must still be captured 'in writing' however electronic methods for documenting consent can be considered to be in writing.
- Following consent, a copy (physical or electronic) of the signed consent form must be provided to the participant. This can be in the format of a non-editable pdf which can be emailed to the participant.
- The participant must be give a contact point for further information about the trial.

ECONSENT FOR OTHER STUDIES (NON-CTIMPS)

- Current guidance does not require the need for a two way interview prior to consent in non-CTIMPs.
- However other requirements when documenting consent should be applied on a risk based manner.

NB: There is currently no specific guidance in relation to Clinical Investigations of Medicinal Devices.

WHAT ARE ESIGNATURES?

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- The 'eIDAS' Regulation (EU) No 910/2014 were established to create an EU legal framework for electronic signatures.
- 'eIDAS' = 'electronic identification and trust services'.
- Defined an electronic signature as 'data in electronic form which is attached to or logically associated with other electronic data and which is used by the signatory to sign'.
- Copied across in to UK law in 2019 by creation of UK eIDAS Regulations, which is comprised of;
    - The Electronic Identification and Trust Services for Electronic Transactions (Amendment etc.) (EU Exit) Regulations 2019
    - Amendment of The Electronic Identification and Trust Services for Electronic Transactions Regulation 2016 (2016 No.696))

WHAT ARE THE RULES GOVERNING ELECTRONIC SIGNATURES?

Electronic signatures can include signatures that are:

- Tickbox plus declarations
- Typewritten
- Scanned
- An electronic representation of a handwritten signature
- A unique representation of characters
- A digital representation of characteristics, for example, fingerprint or retina scan
- A signature created by cryptographic means

Increasingly conclusive

SIMPLE, ADVANCED AND QUALIFIED ELECTRONIC SIGNATURES

- Electronic signatures can be divided into three groups:

- **1. Simple electronic signatures**

e.g. a stylus or finger drawn signature, a typed name, a tick box and declaration, a unique representation of characters and a fingerprint scan.

- **2. Advanced electronic signatures**

uniquely linked to the signatory, are capable of identifying the signatory, allow the signatory to retain control, and are linked to data within the signature that can detect any changes made.

- **3. Qualified electronic signatures**

an advanced electronic signature created by a **qualified electronic signature creation device** (software) which is legally equivalent to a handwritten signature.

- **In most cases (including drug trials) a simple eSignature will suffice.**

Increasingly conclusive

MINIMUM REQUIREMENTS WHEN USING ESIGNATURES IN TRIALS

The method which you use will depend on;

- The nature and complexity of the research
- The risks, burden and benefits of the research
- Any potential ethical issues directly relating to the research.

When deciding which type of eSignature you wish to use, you need to consider the following 4 things

1. Can you can trust that the person signing the eConsent is who they say they are
2. Can you can trust that the form has not been altered in any way
3. Can you can be sure of when the form was completed
4. Can you can demonstrate all of the above if required by audit / inspection

THE USE OF ESIGNATURES IN CTIMPS

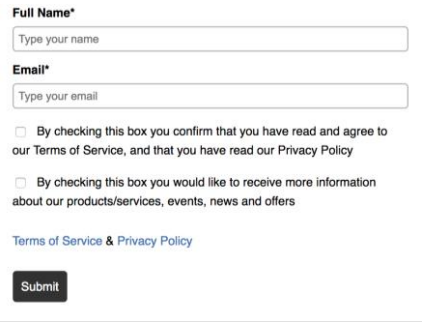
- CTIMPS which involve risks no higher than that of standard medical care (Type A trials), any simple electronic signature may be used (including typewritten or scanned eSignatures)
- CTIMPS which including phase I healthy volunteer trials and involve risks above that of standard medical care (Type B and C trials) must as a minimum use a simple eSignature which involves tracing the participant's handwritten signature using a finger or a stylus.
- These need to be at the quality to permit a comparison to be made in the event of a Sponsor Audit or MHRA inspection.
- For higher risk Type B and C trials, biometric eSignatures should also be considered. In rare cases it made be necessary to use advanced or qualified eSignatures.
- Typewritten or scanned images of handwritten signatures should not normally be used for Type B and C CTIMPs as they are uncontrolled.
- There is a risk, where sites hold files of scanned signatures of patients from previous studies, that these could be used without the knowledge of the participant.

THE USE OF ESIGNATURES IN NON-CTIMPS

- For the majority of other (Non-CTIMP) trials studies a **simple electronic signature** is normally adequate;

- For studies with some associated risk or burden on the participant a **simple eSignatures** involving a handwritten signature using a finger or a stylus should be considered as these allow the signature to be compared to existing eSignatures and/or wet-ink signatures the participant has previously provided.

- For very low risk studies, for example online surveys or questionnaire-based research a consent statement and a tickbox within the survey/questionnaire can be used.



WHY SHOULD I USE ECONSENT?

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Using eConsent offers a number of potential benefits:

- Can improve the understanding of trial participants
  - Interactive nature of information provision can better support learning
  - Can be used to test participant comprehension (knowledge review)
- Can provide feedback on how information and consent materials could be improved
- Can reducing participant burden
  - Can reduce the need to attend visits,
  - Reconsent can occur remotely
  - Less paperwork to keep
- Can reducing researcher burden and errors
  - simplified central monitoring of consent processes
  - Enables easier version control of information
  - Can reduces errors in consent ;

11% of all findings within EMA Inspection Reports between 2008-2012 directly related to consent, a quarter of which related to simple signature and date errors on the consent form which could be prevented by a well designed eConsent system.

Bernabe R, van Thiel G, Breekveldt N, Gispen-de Wied C, van Delden J. Ethics in clinical trial regulation: ethically relevant issues from EMA inspection reports. Curr Med Res Opin. 2018;35(4):637-645. doi:10.1080/03007995.2018.1528214

WHY SHOULD I USE ECONSENT?

Using eConsent offers a number of potential benefits:

- Expectations of participants
  - eConsent is common-place outside of trials (e.g. banking)
- Increasing inclusivity to research

DOES ECONSENT EXCLUDE CERTAIN POPULATIONS?

A perception that eConsent may exclude certain populations from taking part in research;

- Lack of internet access
  - Internet Access much more commonplace
  - Ability to provide internet enabled devices where needed
  - Traditional methods can still be used alongside eConsent

ONS survey - 2020

In January to February 2020, 96% of households in Great Britain had internet access

In January to February 2020, 76% of adults in Great Britain used internet banking.

In January to February 2020, 87% of all adults shopped online within the last 12 months

- Accessibility
  - Redcap already has inbuilt text to speech functionality,
  - Text size can be easily changed
  - Hover-over functionality – explaining terms
  - Coming soon in REDCap – translation module

DOES ECONSENT EXCLUDE CERTAIN POPULATIONS?

From a SWAT evaluating the use of electronic informed consent technology in clinical trials.

"Older participants adapted well to new technology. ***Of patients 60 or older, only 27% had experience with a tablet device.*** *While that could prompt cause for concern,* ***older users universally reported high satisfaction on each eConsent feature****. As a whole, all age groups rated the process "easy" or "very easy" to use and no one with experience using paper forms said they thought the traditional process was better."*

Hilde Vanaken P. eConsent Study Provides Insights to Shape Industry Adoption. Applied Clinical Trials Online. https://www.appliedclinicaltrialsonline.com/view/econsent-study-provides-insightsshape-industry-adoption. Published 2016. Accessed February 15, 2021.

KEY CONSIDERATIONS WHEN USING ECONSENT

- Have you paid attention to the information needs of your patient population. Is electronic information appropriate?
  - Are you going to offer traditional alternatives to your participants if they prefer? (e.g. paper Patient Information Sheets)
  - Is there still the option for face-to-face communication if appropriate?
  - Is your system accessibility friendly?
- How will participants access the information / consent forms?
  - Will you be providing tablets / phones to participants?
  - If they are using their own device is your eConsent system compatible with the OS (Android, iOS, Windows) or browser (Chrome, Safari, Edge)
- What if participants do not have access to their own devices or internet access?
  - Consider budgeting for a certain number of 5g enabled devices to loan to these participants, or having a hybrid system.
  - Will they be locked so they can only be used for trial purposes?
  - Are they secure if lost / stolen?
  - How will you get them back at the end of the process?

KEY CONSIDERATIONS WHEN USING ECONSENT

- Is it possible to verify who is completing the form and where appropriate how will you confirm the person completing the form is who they say they are?
    - In some cases, the patient will be consented on site or will be known to the Investigator however it is possible you will need to confirm they are who they say they are.
- How will you provide the participants with the information to decide whether they wish to take part (pdf, email, YouTube link).
    - If a video this will need to be prepared in advance of the ethics submission.
    - What happens if you need to update it during the trial? Ensure you have the ability to do this.
- Does the eConsent system record when the information and consent form were accessed?
    - This may be audited. Can you demonstrate when this happens or does it need to be written in the patient notes?
- Is it possible to document which version of the information the participant has read?
    - Sites / countries may approve different versions of the patient information media at different times.
    - Can your system deal with multiple versions of the same information sheet?

KEY CONSIDERATIONS WHEN USING ECONSENT

- Is the process of eConsent documented appropriately with an audit trail?
  - How will sites access this data? Will you provide email confirmation relating to this for the patient notes?
- Is the system secure? (especially important where you are collecting personal data such as names etc)
  - Has it been appropriately tested? Is there a risk patients could access other patients data?
- If appropriate, how will you provide the participants with a copy of the completed consent form?
  - Is emailing this appropriate? Can it be printed and posted?
- International Trials - have you checked the country specific regulations relating to eConsent and eSignatures?
  - eSignatures in EU need to follow eIDAS' Regulation (EU) No 910/2014
  - eSignatures in USA need to follow Title 21 of the FDA Code of Federal Regulations, Part 11.

FURTHER INFORMATION

Joint statement on seeking consent by electronic methods

https://www.hra.nhs.uk/documents/1588/hra-mhra-econsent-statement-sept-18.pdf

Guidance HRA Consent and Participant Information Sheet Preparation Guidance

http://www.hra-decisiontools.org.uk/consent/

HRA Guidance: Applying a proportionate approach to the process of seeking consent (2017)
https://www.hra.nhs.uk/planning-and-improving-research/best-practice/informing-participantsand-seeking-consent/

EUCROF - Electronic Informed Consent Implementation Guide Practical Considerations (2021)

https://www.eucrof.eu/images/Electronic_Informed_Consent_Implementation_Guide_Practical_Considerations_Version_1.0___March_2021_2.pdf

THANK YOU