Introduction to eConsent

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Presentation Outline

- Introducing eClinicalForum and EUCROF eConsent Team
- Introducing eConsent Implementation Guide
- What is eConsent
- eConsent Regulatory Overview
- eConsent Considerations
- eConsent and COVID-19

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The eConsent Team

- Is a joint effort between EUCROF and eClinical Forum
- Was formed in 2019, mainly CROs, sponsors, vendors
- An eConsent SME group and forum to ask questions on experiences

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The eConsent Team

Remit - three key deliverables

To provide insight and knowledge sharing around eConsent through:

- Webinars
- Practical Implementation Guide
- Engagement with wider industry and authorities

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eConsent MHRA/HRA Definition

Defined in this instance as:

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

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Reference – MHRA/HRA Joint Statement
https://mhrainspectorate.blog.gov.uk/2018/10/08/econsent/

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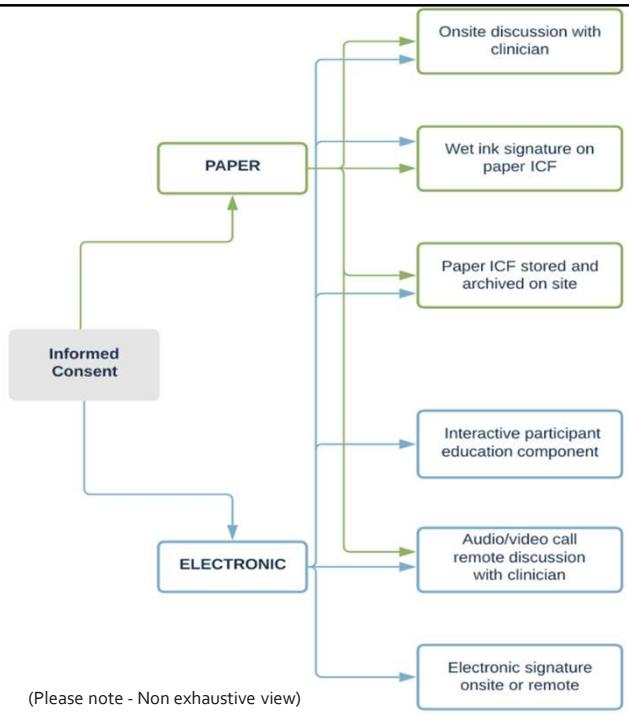
eConsent - Onsite verses Remote Scenarios



(Please note - Non exhaustive view)

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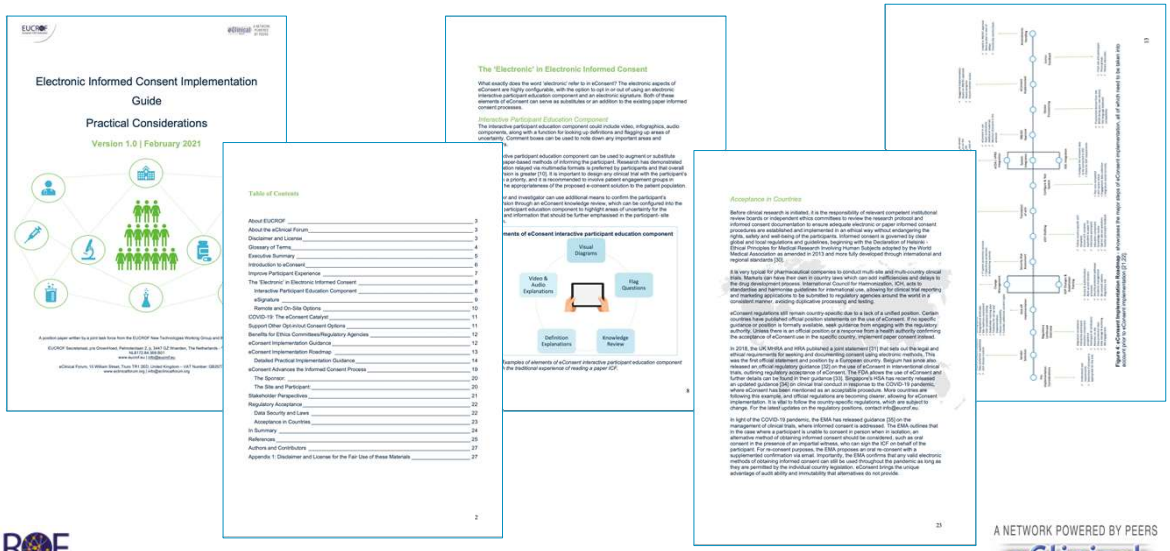
eConsent Implementation Guide Overview



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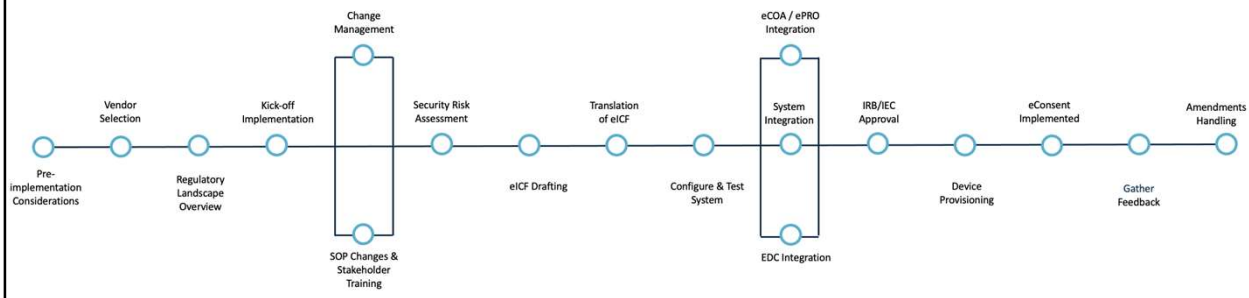
eConsent Implementation Overview



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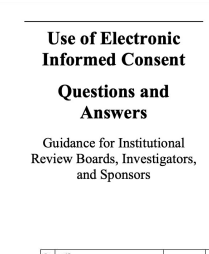
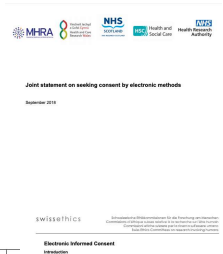
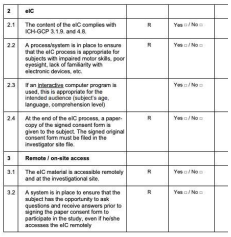
eConsent Regulatory Overview


Use of Electronic Informed Consent

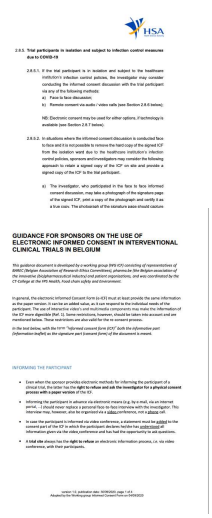
Questions and Answers

Guidance for Institutional Review Boards, Investigators, and Sponsors


Joint statement on seeking consent by electronic methods




Electronic Informed Consent


GUIDANCE FOR SPONSORS ON THE USE OF ELECTRONIC INFORMED CONSENT IN INTERVENTIONAL CLINICAL TRIALS IN BELGIUM

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eConsent Considerations

- Data Protection
- Data Privacy
- Variability of regulations
- Identity Verification
- ROI
- Adoption of new technology

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and finally…COVID-19 the eConsent Catalyst

Interest in remote consent increased significantly since the outbreak of COVID-19

- Remote consent is safer for patients by minimizing travel
- Reduces need to visit the site because of consent or re-consent
- Even if patients are visiting the site, the time spent can be minimized as patients can study the consent form in advance

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THANK YOU

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