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
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

Remit - three key deliverables
To provide insight and knowledge sharing around eConsent through:
- Webinars
- Practical Implementation Guide
- Engagement with wider industry and authorities
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.’

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

eConsent - Onsite verses Remote Scenarios

(Please note - Non exhaustive view)
eConsent Implementation Guide Overview

eConsent Implementation Overview
eConsent Regulatory Overview

Data Protection

Data Privacy

Variability of regulations

Identity Verification

ROI

Adoption of new technology

eConsent Considerations
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

THANK YOU

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