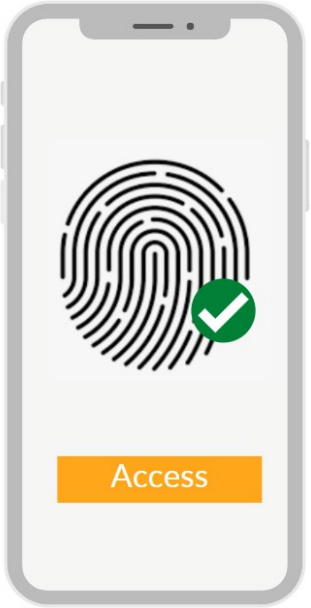
eConsent in Medical Device Clinical Investigations

Broadcast starts at
15.00 CET on Dec. 17th 2020



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Today's Hosts

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Today's Agenda

- Definitions
- eConsent variations
- Compliance
- Case examples
- FAQ and Q&A

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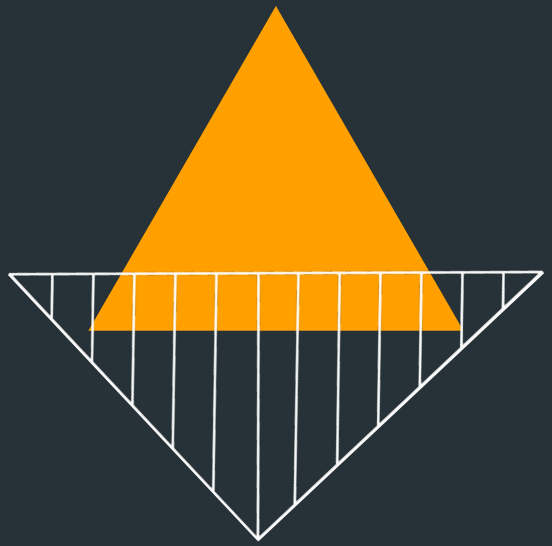
What is a consent?



1. Informed Consent

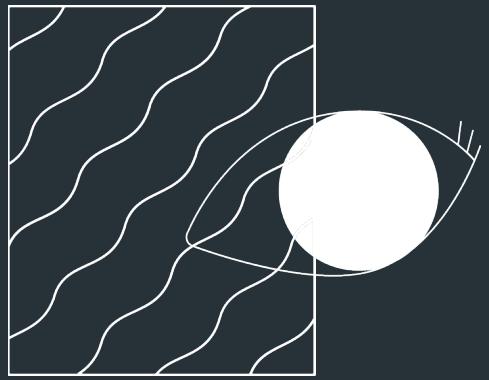
2. Data Processing Consent

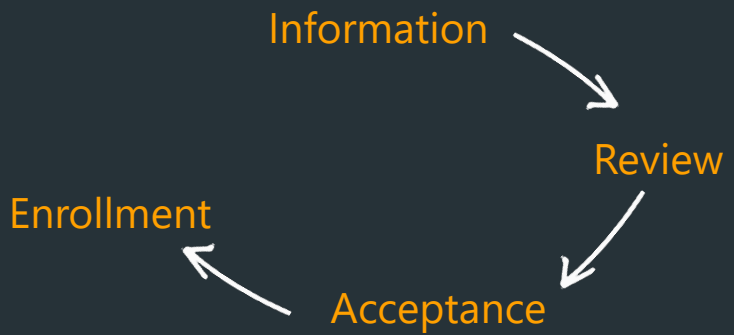
The Consent Process

- Objective
- Rights & Risks
- Ethics
- Acceptance

eConsent

Digital reproduction of the same process



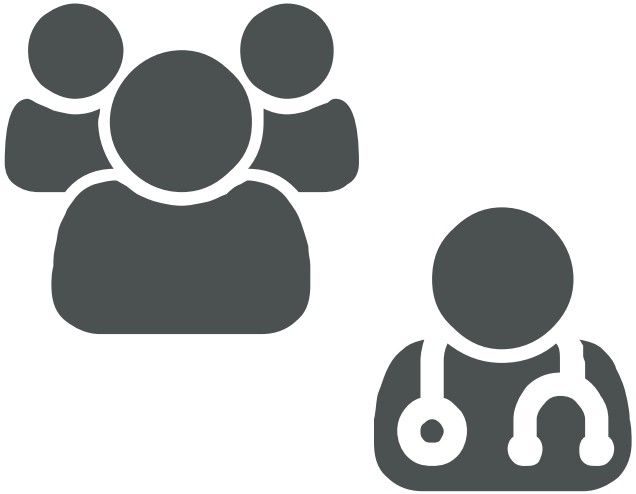


Electronic

Traditional

Actors Involved

- Clinicians
- Patients
- Guardians / relatives



Electronic Signatures

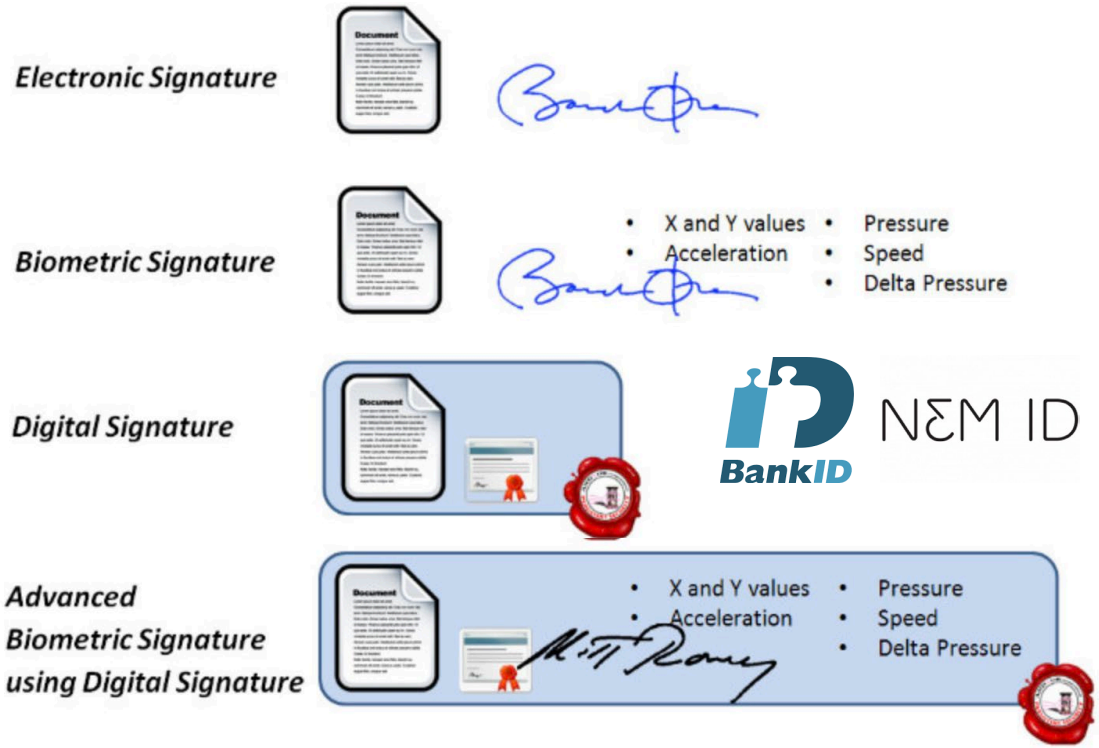


Image source: andxor.com

eConsent

Variations

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eConsent Variations

Subject Only

Subjects “registers” and accepts consent without active involvement

Subject & Investigator Remotely

Subject & Investigator sign remotely (e.g., after a conference call)

Subject & Investigator on-site

Patient & Investigator sign electronically but in person

Regulatory Compliance

What to watch out for

- eConsent vs eSignature
- Most countries accept eConsent
- Not all countries accept both for clinical investigations

Regulatory Compliance

Where is eConsent and eSignatures allowed for clinical investigations

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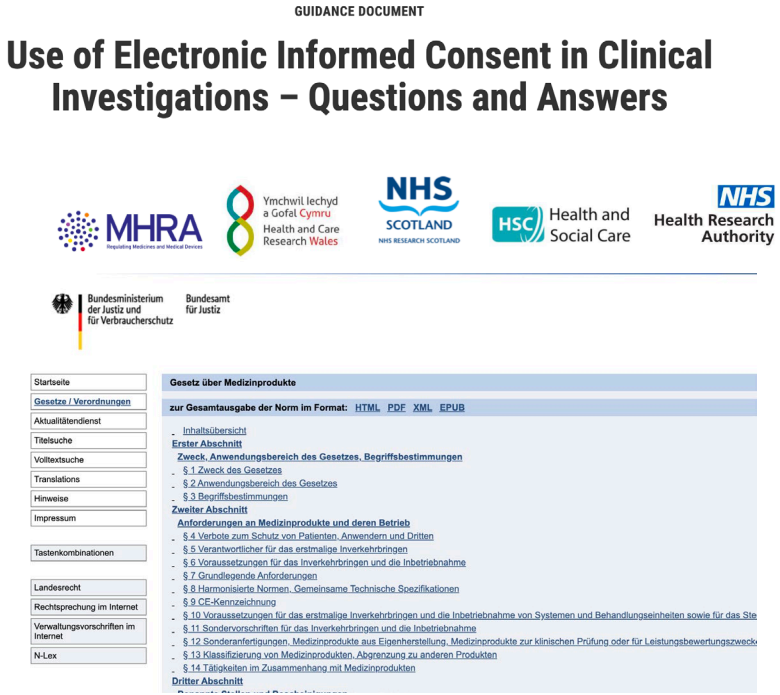
Regulatory Compliance

Guidelines and laws

- FDA Guidance
- Joint statement from MHRA
- German law


GUIDANCE DOCUMENT

Use of Electronic Informed Consent in Clinical Investigations – Questions and Answers

MHRA · Ymchwil Iechyd a Gofal Cymru Health and Care Research Wales · NHS SCOTLAND · HSC Health and Social Care · NHS Health Research Authority

Bundesministerium der Justiz und für Verbraucherschutz · Bundesamt für Justiz

Startseite | Gesetze / Verordnungen | Aktualitätendienst | Titelsuche | Volltextsuche | Translations | Hinweise | Impressum | Tastenkombinationen | Landesrecht | Rechtsprechung im Internet | Verwaltungsvorschriften im Internet | N-Lex

Gesetz über Medizinprodukte

zur Gesamtausgabe der Norm im Format: HTML PDF XML EPUB

- Inhaltsübersicht

Erster Abschnitt

Zweck, Anwendungsbereich des Gesetzes, Begriffsbestimmungen

- § 1 Zweck des Gesetzes
- § 2 Anwendungsbereich des Gesetzes
- § 3 Begriffsbestimmungen

Zweiter Abschnitt

Anforderungen an Medizinprodukte und deren Betrieb

- § 4 Verbote zum Schutz von Patienten, Anwendern und Dritten
- § 5 Verantwortlicher für das erstmalige Inverkehrbringen
- § 6 Voraussetzungen für das Inverkehrbringen und die Inbetriebnahme
- § 7 Grundlegende Anforderungen
- § 8 Harmonisierte Normen, Gemeinsame Technische Spezifikationen
- § 9 CE-Kennzeichnung
- § 10 Voraussetzungen für das erstmalige Inverkehrbringen und die Inbetriebnahme von Systemen und Behandlungseinheiten sowie für das Ste
- § 11 Sondervorschriften für das Inverkehrbringen und die Inbetriebnahme
- § 12 Sonderanfertigungen, Medizinprodukte aus Eigenherstellung, Medizinprodukte zur klinischen Prüfung oder für Leistungsbewertungszwecke
- § 13 Klassifizierung von Medizinprodukten, Abgrenzung zu anderen Produkten
- § 14 Tätigkeiten im Zusammenhang mit Medizinprodukten

Dritter Abschnitt

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Signature Frameworks

eSignature frameworks

eIDAS

Regulation (EU) No 910/2014 establishes an EU-wide legal framework for electronic signatures.

FDA CFR21 Part 11

Regulatory guidance on Electronic Records; Electronic Signatures - Scope and Application

Deciding Factors

- Why do I need eConsent and to what degree?
- What variation suits my study design?
- Where's it supported?

Case

Examples

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Case Example #1

SUBJECT ONLY

COVID-19 Cohort

- All subjects registered online and read Informed consent
- Consent provided using the “Ice-Key” (validated digital signature)
- SMART-TRIAL enrols subject and questionnaires are sent to participants

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Case Example #2

- Device trial fully remote following to MHRA guidelines (other research)
- Built-In SMART-TRIAL “ink like” signature
- eConsent conducted via remote consultation

SUBJECT & PI SIGN REMOTELY

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FAQ

eConsent

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Common Questions

- Do you have to use validated vendor for eSignature?
- How can subjects withdraw their approval?
- Is video consultation always required?
- Can I combine eConsent with paper?

LIVE

Q&A

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