CHANGER

CHALLENGES AND INNOVATIVE CHANGES IN RESEARCH ETHICS REVIEWS

# The legal landscape of e-consent

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Funded by the European Union

CHANGER training May 4th 2026

# What is consent (in legal perspective)?

- **A legally relevant expression of will:** It authorizes actions that would otherwise be unlawful (e.g. medical intervention, data processing)

- **Not a contract,** but a legal justification grounded in fundamental rights

- In research, **it operationalizes**: autonomy, self-determination, human dignity (**ethical principles**)

# Legal sources of informed consent

**International framework**

Oviedo Convention

**EU legal framework**

Clinical Trials Regulation (EU) No 536/2014
→ Consent for participation in research

General Data Protection Regulation
→ Consent for processing personal data

**National legal framework**

# Core requirements

**Free**

- No coercion, pressure

**Informed**

- Adequate, understandable information

**Competent (Capacity)**

- mental ability to understand the risks and benefits

**Additional legal criteria (GDPR context)**

- Specific
- Unambiguous
- Explicit (for sensitive data like health data)

# Data processing consent (GDPR)


Additional constraints:

- Must be **separable** from other matters
- Must be **withdrawable as easily as given**
- Can be invalid in **imbalanced relationships** (e.g. patient–physician)

# Consent for research and data protection: not the same

In the EU, there is a distinction between consent for participation in research and consent for processing the participants' personal data.

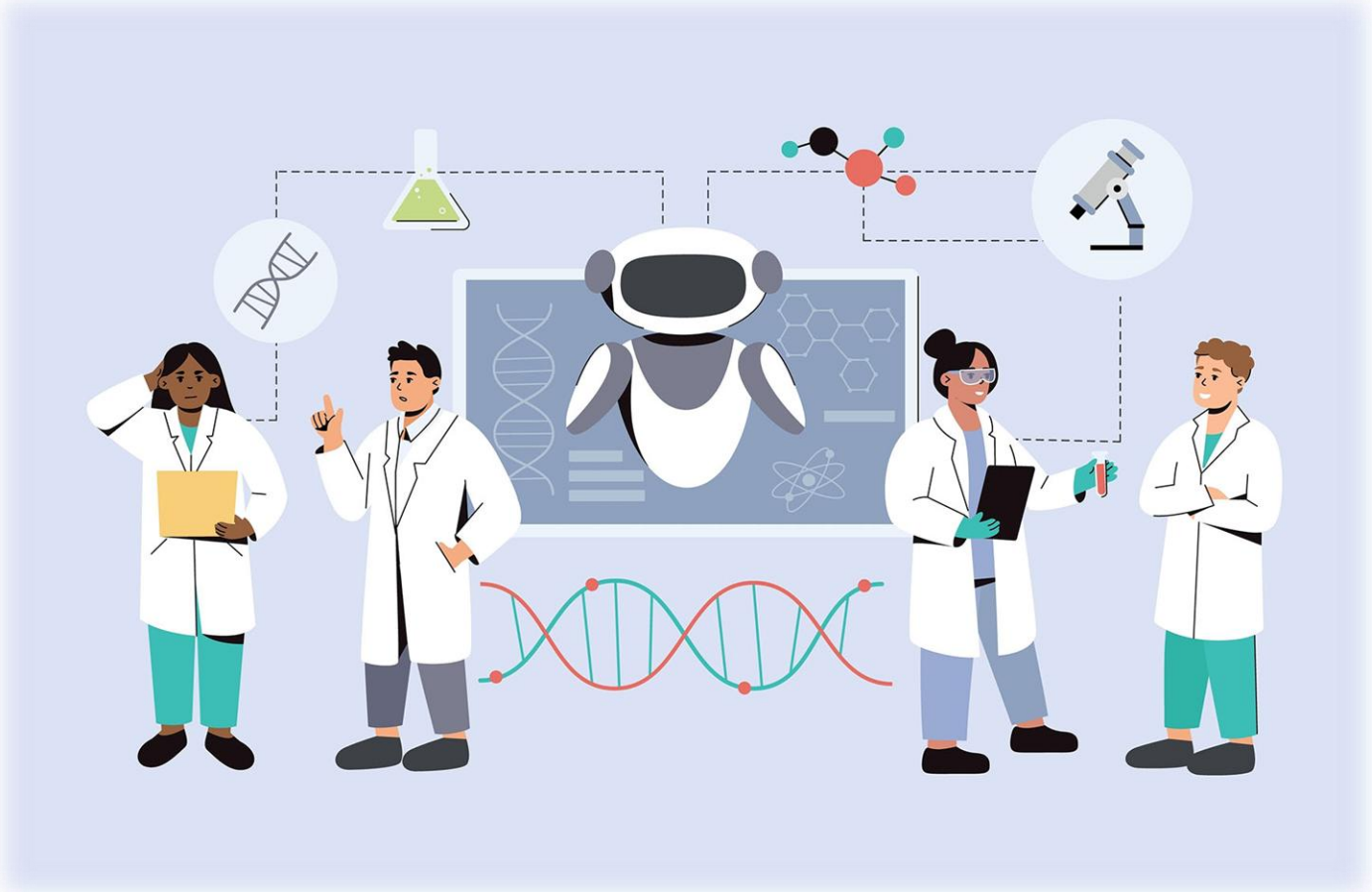
**Imbalanced/dependent situations**

(e.g., employer-employee, physician-patient, public authority-citizen)

| Clinical Trials Regulation | General Data Protection Regulation |
|---|---|
| Consent is required | Consent may not be the proper legal ground, since not freely given.<br><br>Different legal ground might be necessary for processing personal data (e.g., public interest) |

# **Electronic**
# informed consent

# Increasingly relevant in AI-driven and data-intensive medical research



# **Electronic** consent: what changes legally?

**E-consent must still be:** free; informed; given by a capable person

<u>But introduces new legal questions:</u>

**- Identity verification:** Who is actually consenting?

**- Authenticity:** Is the consent document reliable?

**- Integrity:** Has the content been altered?

- **Auditability**: Can consent be proven later?

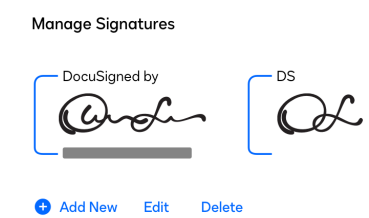
These are **legal validity issues**, not just technical ones

# Electronic signatures

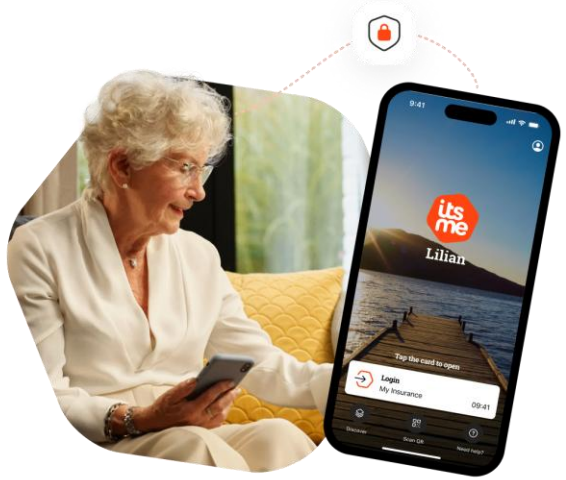
## Simple

## Advanced

docusign




## Qualified



# Legal framework for electronic signatures

**eIDAS Regulation (EU) No 910/2014**

- EU regulation on:
  - Electronic identification
  - Trust services
- Applies directly in all Member States

**Purpose**

- Ensure **legal recognition of electronic signatures**
- Enable **cross-border trust**

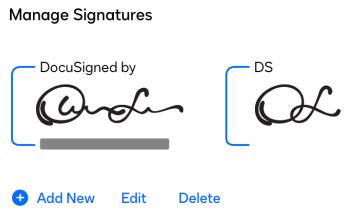
# Types of electronic signatures

**1. Simple electronic signature (SES)**

- e.g. tick box, typed name
- Minimal security

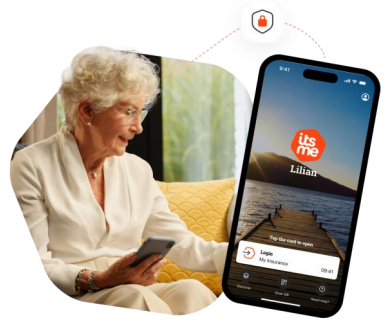
**2. Advanced electronic signature (AES)**

- Uniquely linked to the signer
- Identifies the signer
- Detects changes to the document




**3. Qualified electronic signature (QES)**

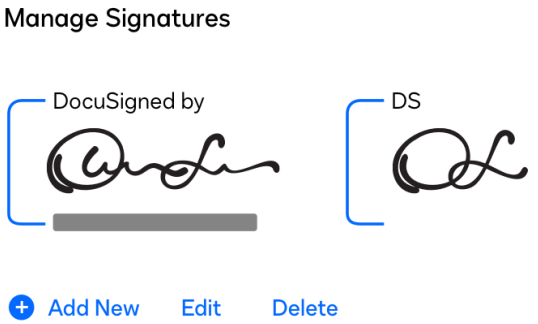
- AES +
- Based on a qualified certificate
- Created with a secure device



# Advanced electronic signature (AES)

**Identity verified via:**

- email + SMS code (2-factor authentication)




**A participant signs an e-consent form using:**

- A secure signing platform (e.g. DocuSign-style system)

The document is cryptographically sealed (any change is detectable)

**If the document is altered → signature becomes invalid**

# Qualified electronic signature

**Identity verified through**:

- government-issued digital identity

**participant signs using:**

- A national eID system (e.g. itsme® in Belgium)

**Signature created via:**

- certified secure hardware/software

**Legally equivalent to a handwritten signature**

| | Simple | Advanced | Qualified |
|---|---|---|---|
| **Short description** | Basic electronic indication of consent | Secure signature linked to signer | Certified signature with highest security |
| **Example** | Click “I agree” in an online form | Signing via platform + email/SMS verification (2FA) | Signing via national eID (e.g. itsme®, BankID) |
| **Identity check** | None / very limited | Moderate (e.g. 2FA) | Strong (government-verified identity) |
| **Integrity** | Limited protection | Document is sealed (tamper-detection) | Fully secured and certified |
| **Legal value** | Valid but weak evidence | Strong evidentiary value | Equivalent to handwritten signature |
| **Use in research** | Low-risk studies, surveys | Common in clinical research | High-risk / high-liability contexts |

# Digitizing the Informed Consent Process: A Review of the Regulatory Landscape in the European Union

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PMCID: PMC9174519 PMID: 35692551

## Abstract

### Background

Rapid technological advancements are reshaping the conduct of clinical research. Electronic informed consent (eIC) is one of these novel advancements, allowing to interactively convey research-related information to participants and obtain their consent. The COVID-19

# Acceptance of eIC in the EU Member States in 2022

On a national level, countries were classified into three groups:

1) countries accepting and regulating the use of eIC,
2) countries accepting the use of eIC without explicitly regulating it, and
3) countries not accepting the use of eIC.

# Acceptance of eIC in the EU Member States in 2022

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~~3) countries not accepting the use of eIC.~~

# The landscape now

Since our research in 2022, a lot has changed.

Historically, some Member States were cautious or restrictive, but:

- There is **no strong evidence today of an EU country explicitly banning eIC**
- The trend (especially post-COVID + digital trials) is toward **acceptance**

If anything, **restrictions are procedural, not prohibitive**

- e.g. requiring:
  - additional verification
  - hybrid consent (digital + in-person)
  - ethics committee approval

# What actually varies across the EU?

Instead of “allowed vs not allowed”, the real differences are:

**Level of regulation**

- Explicit legal framework vs silence + guidance

**Type of e-signature required**

- AES or QES

**Ethics committee strictness**

- Some countries are:
  - permissive
  - others conservative in practice

# Thank you!

For any questions, please feel free to reach out:

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