

Electronic Informed Consent



Agenda for the day

1. Introduction to informed consent
2. Could e-consent be an alternative?
 - Legal landscape
 - Ethical landscape
3. Case study

Informed Consent

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Who am I?



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Index

1. Why we have informed consent
2. What informed consent is
3. Requirements for informed consent

Why do we need it?

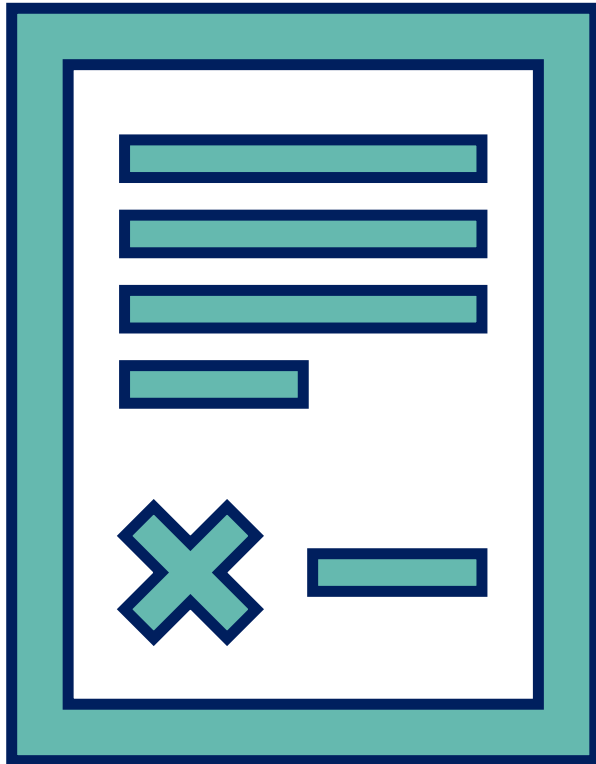


What is informed consent?

*“A freely-taken decision whether or not to participate in a research project, based on careful consideration of the **advantages** and **disadvantages** of such participation **for the person involved**”*

(Shamoo and Resnik, p.263, 2009)

Important distinctions



- Informed consent is **not a contract**
- Informed consent **is not just a form**

Requirements for informed consent

- ✓ Being able to provide consent
- ✓ Being adequately informed
- ✓ Being free from undue influence

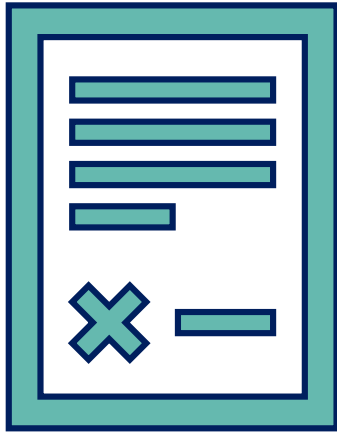


Being able to provide consent

Potential participant needs to be able to provide consent

- **Able to understand information**
- **Able to make decisions based on the information received**

Important distinctions



Legal competency

Ability of an individual to participate in legal procedures

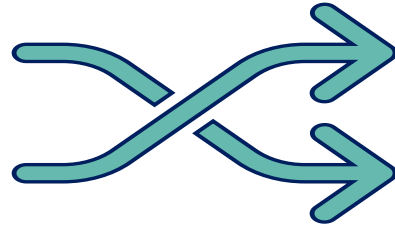


Capacity

“a functional determination that an individual is or is not capable of making a decision within the situation” (Libby et al. 2021)

Being adequately informed

Researchers have an **obligation to inform** potential participants



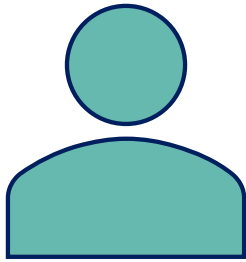
What

- Scientific background
- Risks and benefits (incl. psychological and financial)
- Rights of participants

How

- Comprehensible
- Sensitive to potential participants' needs (e.g., Repeat if needed, give time for questions, to reflect...)

Being free from undue influence



Potential participant

- Free from controlling influence



Researchers need to offer a true choice and avoid

- Force,
- Deceit,
- Fraud,
- Coercion,
- **NB:** check your own bias!

Questions?



Electronic Informed Consent (e-consent)



What is electronic informed consent?

Use of any digital media (such as text, graphics, audio, video, podcasts or websites) to

- Convey information related to the clinical trial to the potential participants
- Document informed consent via an electronic device (such as mobile phones, tablets or computers)

(EMA)

Demo video

