



# Development and implementation of electronic informed consent for cancer research

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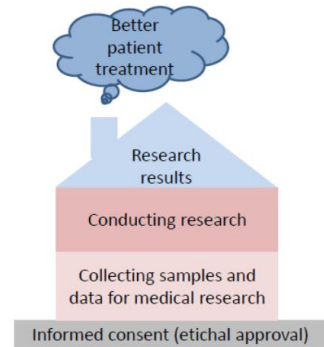
Nordic Biobank Conference 2022

# Conflict of interest

I declare no conflict of interest.

# Background

- Absolute demand since the 1940ies
- Aiming to inform the participants
- Enable them to make an educated decision on participating in medical research
-  Overall aim is to treasure their integrity and autonomy
  - How do we carry out this process?
  - Traditionally collected as a paper document
  - Limited knowledge base on digitalizing the process
  - In spite of the daily use of electronic solutions in our everyday life!



# Definition

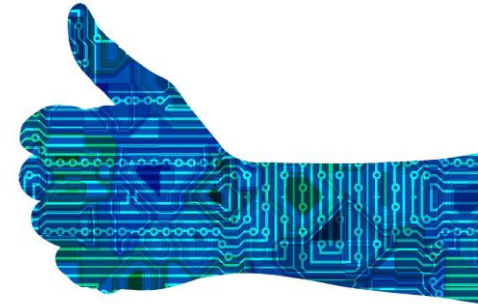
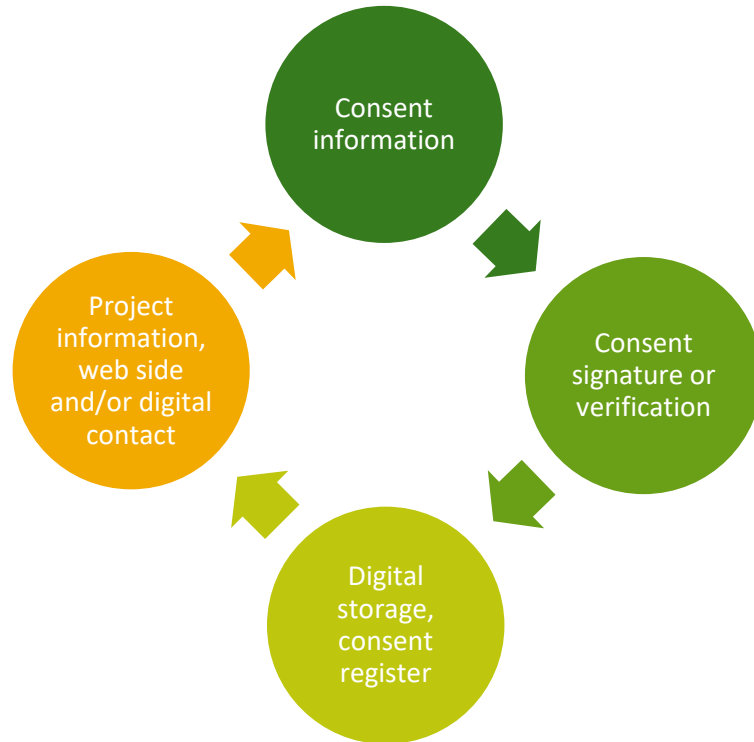
Electronic informed consent refers to the use of electronic systems and processes that may employ multiple electronic media, including text, graphics, audio, video, podcasts, passive and interactive web sites, biological recognition devices, and card readers to convey information related to the study and to obtain and document informed consent.

US Food and Drug Administration



*We need to design an end-to-end solution!*

# The digitalized consent process



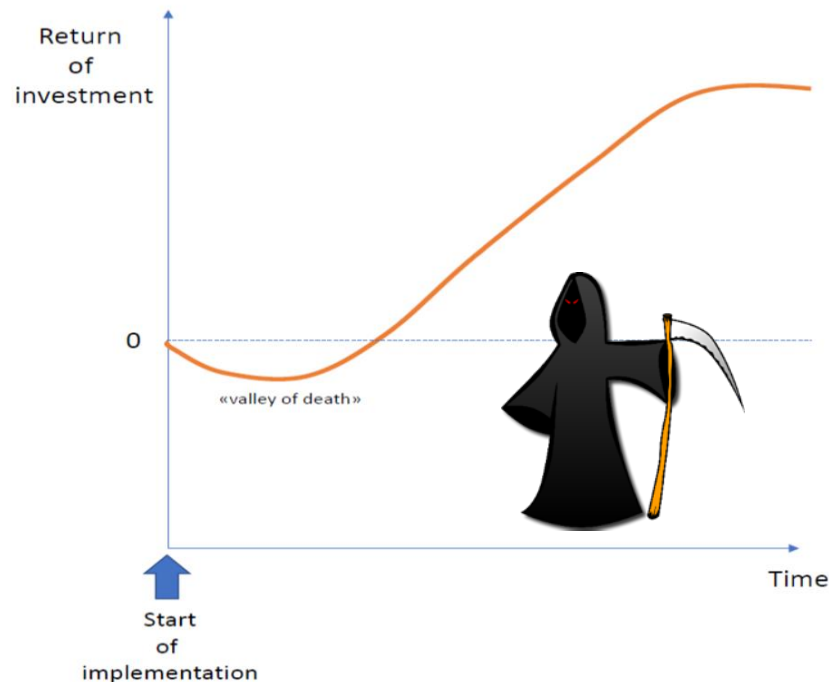
# Ethics and new technology

- **Are we digitalizing one generation too early?**
- The cancer patients are in general elderly
- Adults aged 50-74 account for more than half of all new cancer cases, and elderly people aged 75 and more account for more than a third (UK and in the Nordic countries)
- The technical affiliation might be age dependent
- Additional ethical considerations related to economic situation, physical challenges, mental challenges, illiterate, or other reasons for not being electronic-affiliated



# Efforts and challenges

- At Oslo University Hospital about 8500 cancer patients visit per year
- Hospital with 4 locations
- Cancer patients represent a large and heterogeneous group, differing in sex, age and physical condition



# The SWOT

Internal

## Strengths

- Better workflow
- Increased participation
- Use of technology to increase and evaluate participant understanding
- Systematic and safe storage of consent information
- Transform to digital log-on considered gold standard
- Less time consuming for staff
- Reduction of paper trail and need for storage capacity

## Weaknesses

- Face-to-face communication might be lost or reduced
- Pressure to participate due to technical assistance needed
- Difficulties related to giving digital signature
- Wrongful clicking
- Digital privacy issues
- Lack of in-house technical support
- Comprehensive staff training
- Lack of funding

External

## Opportunities

- Everyday devices as platforms
- Comparable with other solutions in the society
- Consenting from remote location possible
- Consenting process may take place in social setting with unlimited access to information
- More time to decide
- Associated with a quality, high-tec hospital
- Efforts on sustainable national platforms possible

## Threats

- High implementation costs
- Limited technical affiliation or access by participants
- Loss of Wi-Fi, server failure or other technical glitches
- Hard to predict demographic differences
- Skimming of digital consent information without reading
- Overload of digital/ web information in general
- Unpredictable consequences related to digitalization (commercial adds, third party access or information sharing)
- Technical evolution may cause loss of compatibility

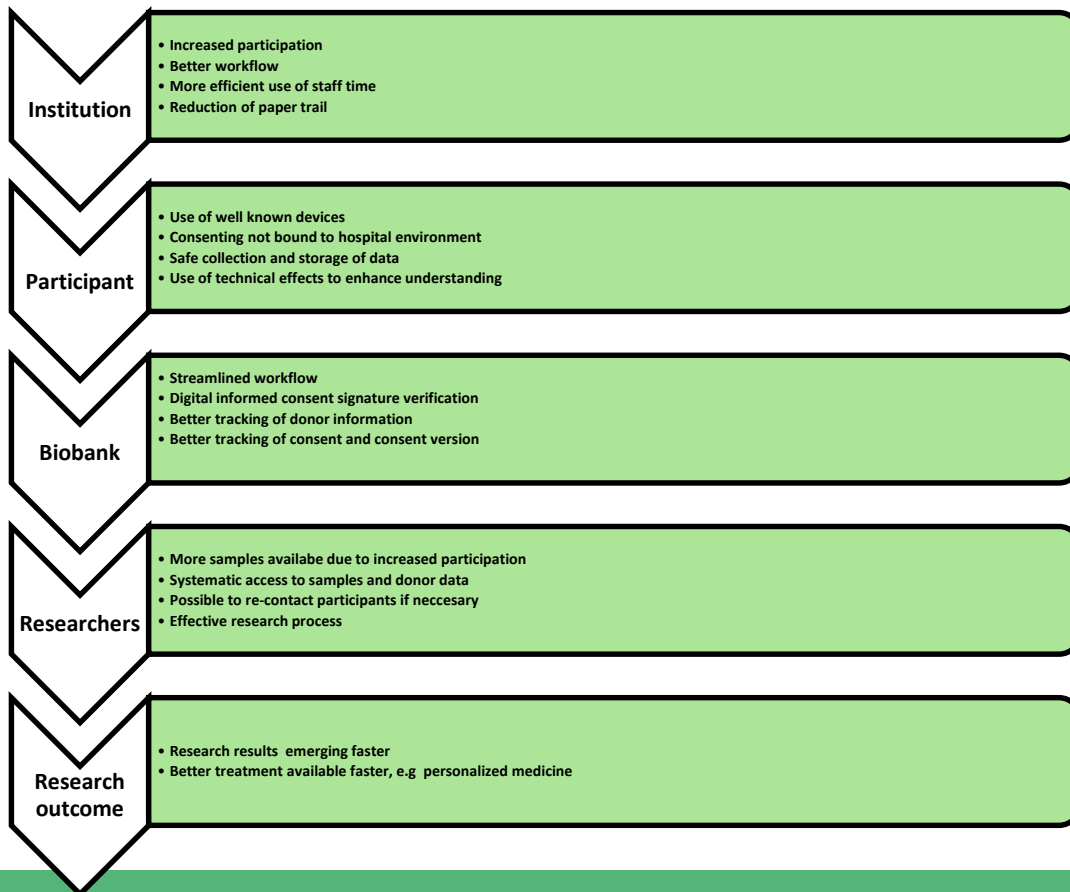


# One click away....

- **The electronic consent solution is not a new technology on its own, but rather use of existing technology in a new way**
- How to provide technical assistance without pressure to participate?
- The use of commercial platforms might have unpredictable consequences (commercial adds, third party access or data sharing)
- In a survey of apps that can function as informed consent platforms, there was found that 8 of 26 apps did not have a statutory of the redistribution or selling of data (Mhealth Uhealth. 2017 Aug 30;5(8)).
- Lost awareness of what we are consenting to due to maneuvering pop up windows with privacy declarations online on a daily basis.



# The value chain



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