

# Governance of (big) health data research

The need for public accountability and interaction  
with society



# Push to amend informed consent requirements



## Legitimate arguments

- science as a public good
- reduce bureaucratic burdens
- limited effectiveness of informed consent procedures
- 'datasolidarity' / social contract arguments

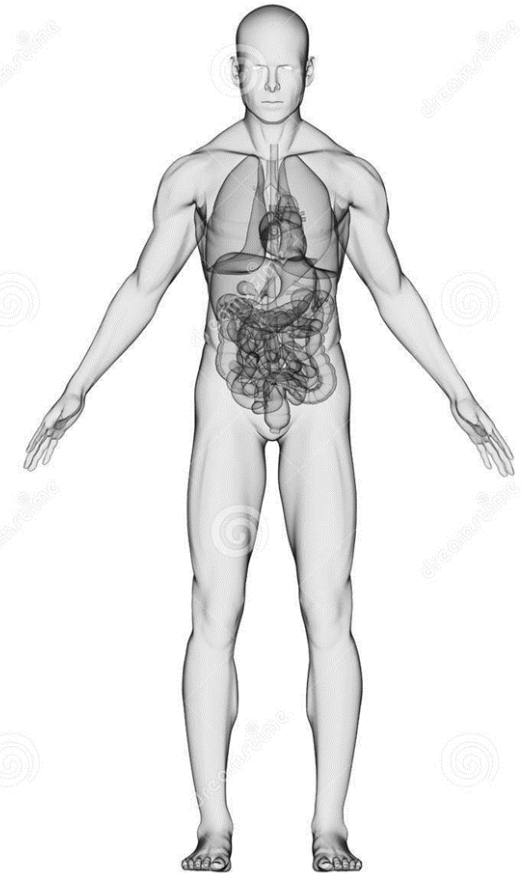
# The transparent patient

From clinical research data to electronic health records

Database linkage and advanced data capture

From anonymization to pseudonimization

From national to global context



# The informed consent discussion

Focus on interpretation of the GDPR

Focus on scientific arguments

Lack of harmonization of principles for governance

Limited engagement with patients and the public

# The public perspective



Widespread support

Motivated by service to the common good and to help other (and future) patients

## Support is conditional

Social value, privacy, minimising risks, transparency, control, information, trust, responsibility and accountability

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SCIENCE 06.07.2016 05:21 PM

## **NHS care.data scheme closed after years of controversy**

NHS England was criticised for poorly explaining the purpose of the scheme after more than one million people opted-out

# Ethical Governance: beyond compliance



Legal compliance does not necessarily command social legitimacy

Need for a 'social license to operate'

# Social license to operate



Drawn into health data domain by Carter et al. , developed further by our group

*“the non-tangible societal permission or approval that is granted to researchers and research organisations. This allows them to collect, use, and share health data for the purpose of health research by virtue of those activities being trustworthy”*

# Promises of a social license



Responsible and sustainable practice

Lessen need for rules and regulations

Fulfils a communicative, informational and educational need towards both practitioners and the public

Opens up learning possibilities for the researchers



# Towards a new (extended?) mandate



- Acknowledge trust as pivotal:
  - liberties granted by social license are based on trust
- Trustworthiness comes with duties
  - to act in line with the values of the data-subject communities and the public
- Promote public values
  - transparency, reciprocity, inclusivity and service to the common good

# Literature



Kalkman, S., Mostert, M., Gerlinger, C. *et al.* Responsible data sharing in international health research: a systematic review of principles and norms. *BMC Med Ethics* **20**, 21 (2019)

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# More info



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