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# **The principles forming the basis of the laws that govern health registry research**

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# Navigating data processing



# **GDPR: Increased harmonization which allows for increased collaboration**



**REGULATION (EU) 2016/679 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL**

**of 27 April 2016**

**on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation)**



# Objectives



# Scientific research

By coupling information from registries, researchers can obtain new knowledge of great value with regard to widespread medical conditions such as cardiovascular disease, cancer and depression. On the basis of registries, research results can be enhanced, as they draw on a larger population. Within social science, research on the basis of registries enables researchers to obtain essential knowledge about the long-term correlation of a number of social conditions such as unemployment and education with other life conditions. Research results obtained through registries provide solid, high-quality knowledge which can provide the basis for the formulation and implementation of knowledge-based policy, improve the quality of life for a number of people and improve the efficiency of social services. In order to facilitate scientific research, personal data can be processed for scientific research purposes, subject to appropriate conditions and safeguards set out in Union or Member State law. (GDPR Rec. 157)

# What keeps research ethicists up at night? – or, what is the normative bedrock of research ethics currently under threat?



# What is harm?



# Foundational focus





## What is a principle?

- Abstractions denoting the pith and basic thrust of a set of legal rules
- At the same time, they have a normative force of their own:
  - Legal rules in their own right
  - Guiding standards, e.g. when conducting interest-balancing
  - Help to shape the drafting of new data privacy codes

Bygrave (2015)

# 1. Lawfulness, fairness and transparency principle

Personal data shall be processed lawfully, fairly and in a transparent manner in relation to the data subject (GDPR Art. 5(1)(a))



# Lawfulness



# Fairness



# Transparency



## 2. Purpose limitation principle

Personal data shall be collected for specified, explicit and legitimate purposes and not further processed in a manner that is incompatible with those purposes; further processing for archiving purposes in the public interest, scientific or historical research purposes or statistical purposes shall, in accordance with Article 89(1), not be considered to be incompatible with the initial purposes (GDPR Art. 5(1)(b))

# Purpose limitation



# Prinsippets dimensjoner

## *CHAPTER II*

### *Principles*

#### *Article 5*

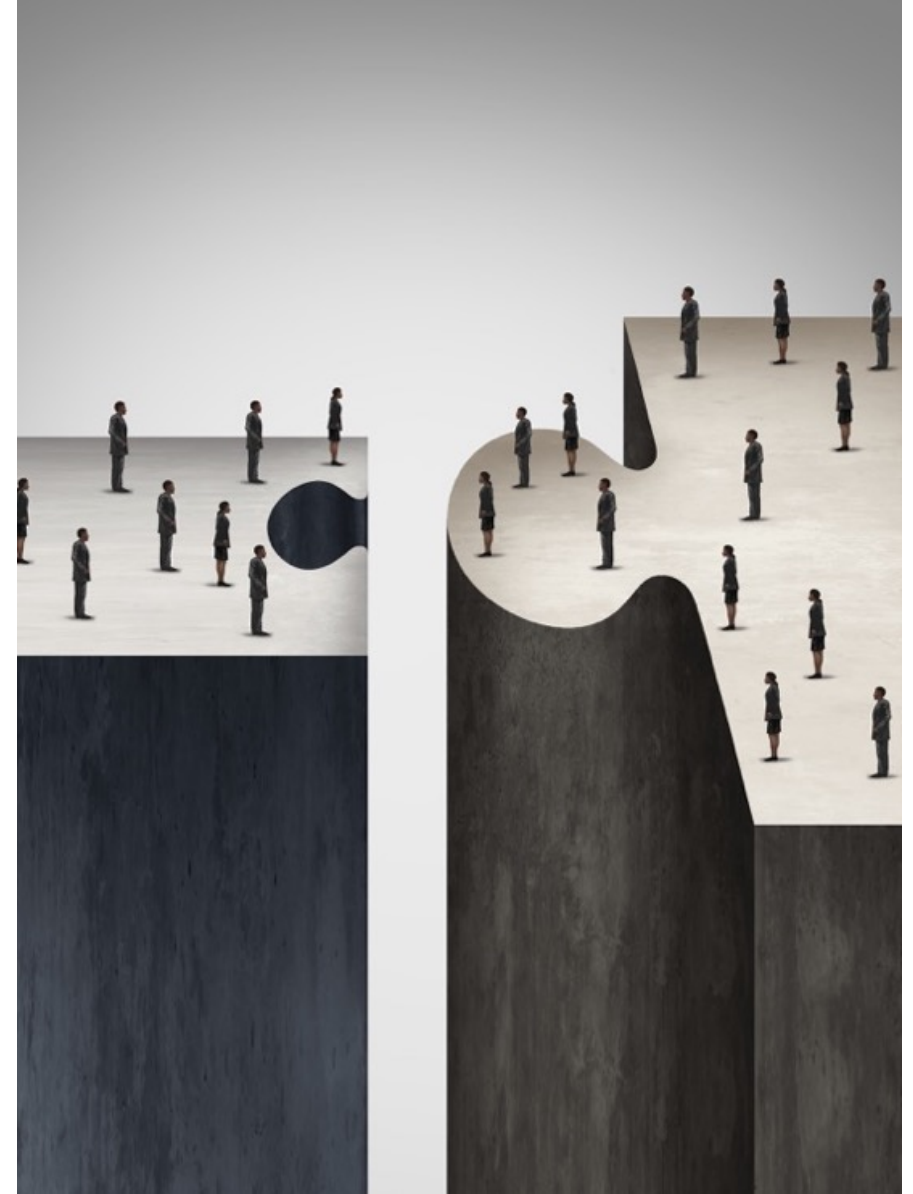
#### **Principles relating to processing of personal data**

1. Personal data shall be:

- (b) collected for specified, explicit and legitimate purposes and not further processed in a manner that is incompatible with those purposes; further processing for archiving purposes in the public interest, scientific or historical research purposes or statistical purposes shall, in accordance with Article 89(1), not be considered to be incompatible with the initial purposes ('purpose limitation');



# Purpose limitation: specification + compatibility

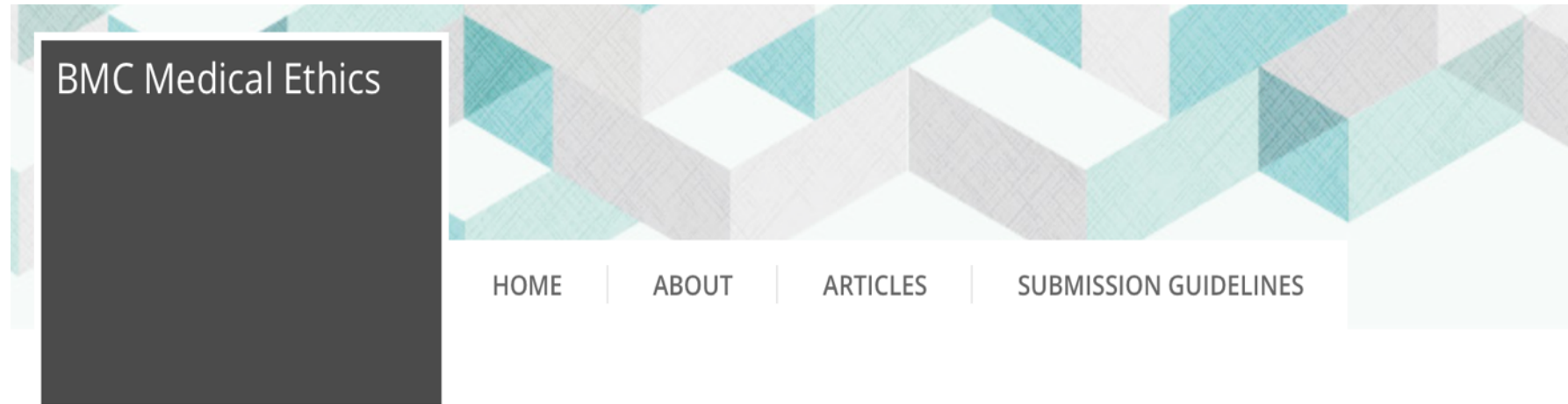


**Unntakene:** further processing for archiving purposes in the public interest, scientific or historical research purposes or statistical purposes shall, in accordance with Article 89(1), not be considered to be incompatible with the initial purposes



Bentzen HB.  
*In the name  
of scientific  
advancement.*  
Forthcoming,  
Intersentia  
2020

# You are not the only one interested in these data



REVIEW | [OPEN ACCESS](#) | OPEN PEER REVIEW

## If you build it, they will come: unintended future uses of organised health data collections

[Kieran C. O'Doherty](#)  , [Emily Christofides](#), [Jeffery Yen](#), [Heidi Beate Bentzen](#), [Wylie Burke](#), [Nina Hallowell](#), [Barbara A. Koenig](#) and [Donald J. Willison](#)

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# Norway: The NOKAS case



# Sweden: The Anna Lindh case



# The consequences for the NBS biobank



NYFØDTPRØVER

## Evig lagring – en trussel mot personvernet

DAGENS  
**Medisin**

Ny

Regjeringen vil lagre blodprøver fra nyfødte til evig tid. Dessverre vil et slikt register også være det ideelle genetiske diskrimineringsverktøy. Kan vi være sikre på at misbruk aldri vil skje?

NYFØDTSSCREENING

# – Tilliten til nyfødtscreeningen står på spill

Publisert: 2018-01-25 05.02 Skrevet av: Gunnar Houge/Trine Elisabeth Prescott

Fagmiljøet er overrasket over at regjeringen vil lagre nyfødtblodprøver til evig tid.

# Other: Biological kinship disputes, mass casualty events, immigration, prioritization, etc





### **3. Data minimisation principle**

Personal data shall be adequate, relevant and limited to what is necessary in relation to the purposes for which they are processed (GDPR Art. 5(1)(c))

# Data minimisation



1984



## 4. Accuracy principle

Personal data shall be accurate and, where necessary, kept up to date; every reasonable step must be taken to ensure that personal data that are inaccurate, having regard to the purposes for which they are processed, are erased or rectified without delay (GDPR Art. 5(1)(d))

# Accuracy



## 5. Storage limitation principle

Personal data shall be kept in a form which permits identification of data subjects for no longer than is necessary for the purposes for which the personal data are processed; personal data may be stored for longer periods insofar as the personal data will be processed solely for archiving purposes in the public interest, scientific or historical research purposes or statistical purposes in accordance with Article 89(1) subject to implementation of the appropriate technical and organisational measures required by this Regulation in order to safeguard the rights and freedoms of the data subject (GDPR Art. 5(1)(e))

# Storage limitation



## 6. Integrity and confidentiality principle

Personal data shall be processed in a manner that ensures appropriate security of the personal data, including protection against unauthorised or unlawful processing and against accidental loss, destruction or damage, using appropriate technical or organisational measures (GDPR Art. 5(1)(f))



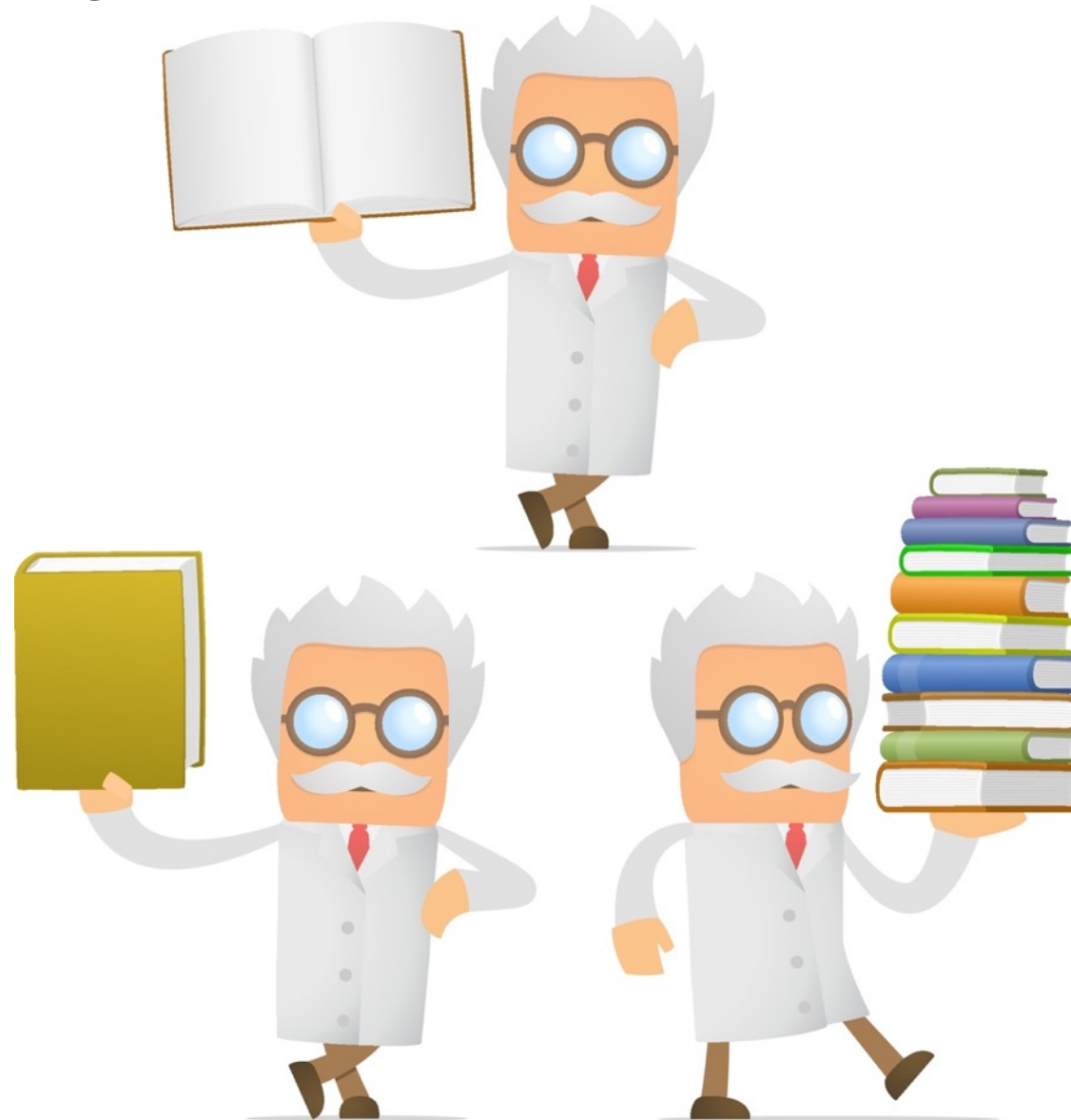
# Integrity and confidentiality



## 7. Accountability principle

The controller shall be responsible for, and be able to demonstrate compliance with, paragraph 1 (GDPR Art. 5(2))

# Accountability



# Thank you for your attention

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Norwegian  
Cancer  
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