

WEON 2018

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COREON (1)

- What is COREON?
- CO = Commissie (Committee)
- RE = Regelgeving (Regulation)
- ON = Onderzoek (Research)

<https://www.federa.org/over-coreon> (in Dutch)



COREON (2)

- The ambitions of COREON
- It wants to achieve a favorable climate for observational health care research
- Taking in account:
 - the public interest of improving care and prevention;
 - without unnecessary obstacles.
- It strives for legislation and regulations concerning health care research that:
 - safeguards patients' interests;
 - promotes careful and responsible research with health data;
 - take into account the interests of scientific researchers;
 - is workable for the researchers;
 - ensures a healthy regulation climate.



COREON (3)

- Who is in this committee?



ELSI (1)

National Service Desk for ethical, legal and social (ELSI) issues about Personalized Medicine ‘ELSI Servicedesk’

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Welkom op de ELSI Website

De nationale Servicedesk helpt onderzoekers, professionals, ethici, juristen, beleidsadviseurs, patiënten en patiëntvertegenwoordigers om problemen op het gebied van ELSI (Ethical, Legal, Social Implications) aan te pakken door informatie en advies beschikbaar te stellen.

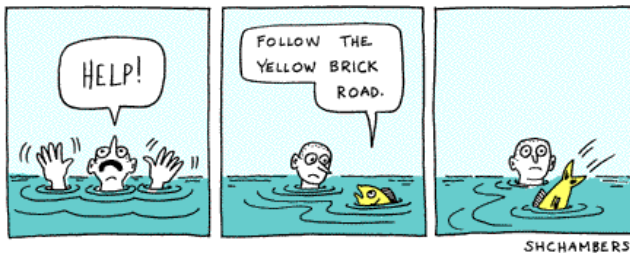


- www.elsi.health-ri.nl



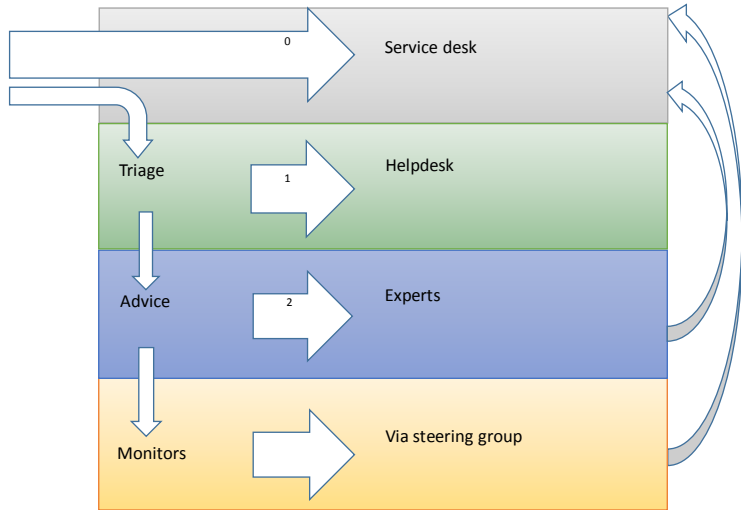
ELSI (2)

- Why do we need this?



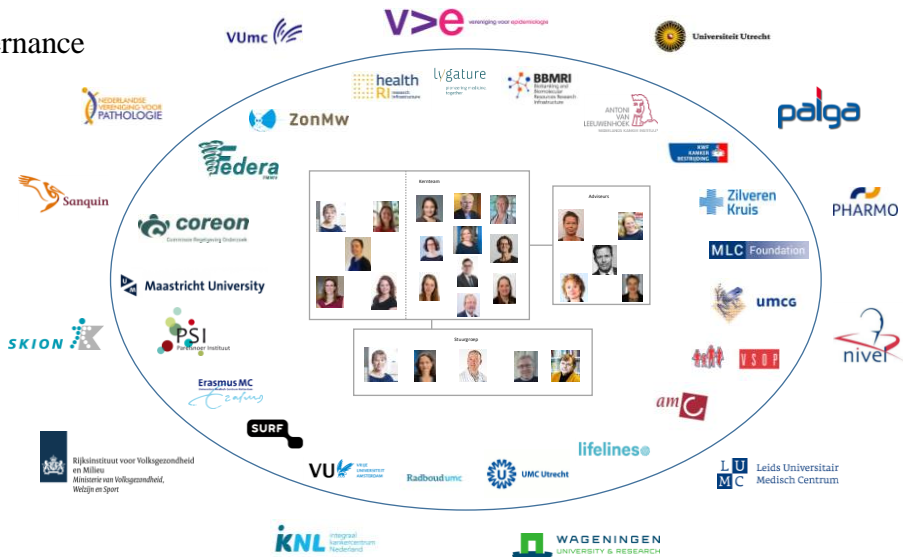
ELSI (3)

- Triage



ELSI (4)

- Governance



GDPR statements (1)

1. Statements

Personal data or not (see later)

2. Guidelines

more complex: do you always need to obtain informed consent? Also when research is conducted with mentally incapacitated patients?

3. The Code of Conduct for the Use of Data in Health Research

<https://www.federa.org/codes-conduct>



GDPR statements (2)

The GDPR relates to personal data.

- What is personal data?
- Is anonymous data personal data?
- Is pseudonymised data personal data?



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GDPR statements (3)

What is personal data?

Definition (art. 4.1 GDPR)

- Any information relating to an identified or identifiable natural person ('data subject')
- An identifiable natural person is one who can be identified, directly or indirectly, in particular by reference to an identifier such as a name, an identification number, location data, an online identifier or to one or more factors specific to the physical, physiological, genetic, mental, economic, cultural or social identity of that natural person.

GDPR statements (4)

Recital 26

- Personal data which have **undergone pseudonymisation**, which could be **attributed to** a natural person by the use of **additional information** should be considered to be information on an identifiable natural person.
- **To determine** whether a **natural person is identifiable**, account should be taken to **all means reasonably likely to be used**, such as singling out, either by the controller or by another person to identify the natural person directly or indirectly. To ascertain whether means are reasonably likely to be used to identify the natural person, account should be taken of **all objective factors**, such as the **costs** of and the **amount of time required** for identification, taken into consideration **the available technology** at the time of the processing and **technological developments**.

GDPR statements (5)

Anonymous data

- Working Party 29 (now: *European Data Protection Board*)
 - 2014: anonymization must be **irrevocable** and re-identification must **not be possible**.
- Court of justice of the EU
 - 2016 Breyer case ro. 46: if the identification of the data subject was prohibited by law or practically impossible in account of the fact that it requires **a disproportionate effort** in terms of **time, cost and man-power**, so that the risk of identification appears in reality to be insignificant.

GDPR statements (6)

Pseudonymised data

- Recital 26
 - Personal data which have **undergone pseudonymisation**, which could be **attributed to** a natural person by the use of **additional information** should be considered to be information on an identifiable natural person.
- Re-identification (case by case)
 - Kind of pseudonymization (techniques)
 - Which data is visible under the pseudonym

GDPR statements (7)



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Conclusion: Personal data or not

- Any information relating to an identified or identifiable natural person.
- Identification without disproportionate time and effort is reasonably possible.