

**PREVENTION OF THE ONSET OF DISORDERS
BY LIFESTYLE CHANGES
WHY SMALL CHANGES MATTER**

Introduction

In het land van bitterbal en boterkoek.

Oratie uitgesproken door

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bij de aanvaarding van het ambt van hoogleraar in de
diabetologie, in het bijzonder
de neuro-endocriene regulatie van diabetes en overgewicht
aan de Universiteit Leiden
op dinsdag 15 april 2008.

Gezonder leven én blijven genieten

FoodFirst Network adviseert over voeding,
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Agenda

The patient and consumer data perspective

- Applicable framework to processing personal data
- Distinction between regular and special categories of data
- Requirements for processing special data in a scientific and in a commercial setting

Dutch Life Sciences
c o n f e r e n c e

Applicable framework to processing personal data

General Data Protection Regulation

- As of May 2018, processing personal data is governed by the GDPR (Regulation 2016/679)
- **Personal data:** any information relating to an identified or identifiable person.
- **Processing personal data:** Collection / storage / structuring / adaptation / consultation / transmission / destruction
- Both doing research re. lifestyle medicine and offering online commercial health services imply the processing of personal data.



Different categories of data under GDPR

Distinction between “regular” and “special” personal data

- Examples regular personal data: name / address / age
- Examples special categories of personal data: health data / biometric data / genetic data
- **Health data:** personal data related to physical or mental health of a natural person, including the provision of health care services, which reveal information about his / her health status.
- **Genetic data:** personal data relating to inherited or acquired genetic data providing unique information on physiology or health, obtained from biological sample.

Different categories of data under GDPR

Processing of personal data is permitted, provided that... (art. 6 GDPR)

- ...this is done on a legal basis, for instance processing is necessary for the performance of a contract / for the purposes of the legitimate interests pursued by the controller

Processing of data concerning health is prohibited, unless.... (art. 9 GDPR)

- ... specific conditions have been met, for instance the data subject has given explicit consent for one or more specific purposes / processing is necessary for scientific research purposes.

Processing special data under GDPR

Scientific setting

Scientific research is an acceptable legal ground for processing health data under art. 9.2 (j) GDPR, provided that the following requirements are met:

1. Processing is necessary;
2. The scientific research serves the general interest;
3. Requesting explicit consent is impossible or it requires disproportionate effort;
4. The processing provides for appropriate warranties that the personal life of the data subject is safeguarded.

(art. 24 Dutch Act implementing GDPR)

Processing special data under GDPR

In a commercial setting: consent required

- ✓ Freely given: real option, conditionality does not meet this test.
- ✓ Specific: if and when consent is required for various purposes, consent must be obtained for each of them.
- ✓ Informed: who will process my data? For what purpose? In which way? How can I withdraw my consent? NB It shall be as easy to withdraw as to give consent.
- ✓ Unambiguous: requires a clear statement or clear affirmative act.

Article 29 Working Party
Guidelines on consent under Regulation 2016/679

Adopted on 28 November 2017

As last Revised and Adopted on 10 April 2018

Processing special data under GDPR

Consent under the Clinical Trials Directive is not the same as under the GDPR

- Clinical trials are conducted, In order to demonstrate measurable health effects of medicinal products or personalized nutrition.
- In a clinical trials setting, the participant need to provide his / her informed consent in writing.
- Such consent covers the participation in a clinical study, including certain invasive actions and the possibility of being administered a placebo.
- This is not the same as processing personal data, which should be covered separately.

Conclusions



- For the future of care, we will need more health research and health related services.
- In both cases, health data will be processed.
- In order to comply with the GDPR, make sure the requirements for processing are not only met, but also well documented.
- In scientific setting, clearly distinguish between GDPR and clinical trial requirements.

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Background AXON Lawyers

Who are we? We are an Amsterdam-based niche firm targeting the life sciences.

What do we do? We assist companies and organizations in the trade of innovative food products, medicinal products and medical devices.

How? Regulatory advice / commercial contracts / dispute resolution

And what else? We report current developments in the field of food law at our blogs FoodHealthLegal and Medical Devices Legal.



Food Health Legal
legal and regulatory blog

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