



GDPR



in a Nutshell

What is this about?

- May 25th 2018: **EU General Data Protection Regulation (GDPR)**
- Other regulations:
 - **Act on Processing of Personal Data** (persondataloven)
 - Public administrations:
 - **Executive Order on Security**
 - **ISO27001** (since 2014)
 - Research: **Act on Research Ethics** (specific guidance on health projects)



GDPR

- Increased **data subject rights**
- Data subjects inside the EU (regardless of where processing occurs)
- Data controllers (principal responsible party)
- Data processors (on behalf of controller)
 - ‘data processing agreements’
- **Penalties** (up to 4% of annual turnover)

(Source: <https://www.gdpreu.org/>)

What is Personal Data?

- any information
- relating to
- an identified or identifiable
- natural person

(more specific national laws might apply)

Personal Identifiable Information (PII)

(Source: Article 29, Data Protection Working Party: Opinion 4/2007 on the concept of personal data)

What is Personal Data?

Any information:

- subjective or objective
- need not be true
- not only 'sensitive' data
- in whatever form (digital, paper, ...)

(**Source:** Article 29, Data Protection Working Party: Opinion 4/2007 on the concept of personal data)

What is Personal Data?

Relating to:

- an individual or objects they own
- for it to 'relate' to an individual
 - content element ('about')
 - or, purpose to evaluate or influence an individual
 - or, results in an impact on rights or interests of an individual

(Source: Article 29, Data Protection Working Party: Opinion 4/2007 on the concept of personal data)

What is Personal Data?

Identified or identifiable:

- able to distinguish from other members of the group
 - directly
 - indirectly (by combining information)
- depends on context
 - more than mere hypothetical possibility
 - likely to be used (cost, purpose, risk)

(Source: Article 29, Data Protection Working Party: Opinion 4/2007 on the concept of personal data)

What is Personal Data?

Natural person (also depends on national legislation):

- living individuals
- no legal persons (businesses)

(**Source:** Article 29, Data Protection Working Party: Opinion 4/2007 on the concept of personal data)

Consent

- Processing is only allowed when:
 - **Consent**
 - ≠ informed consent for health projects
 - Freely given, legible, purpose specific
 - by ‘clear affirmative action’
 - Required
 - contract
 - legal obligation
 - protect vital interests
 - task in public interest

(Source: “The ABC of GDPR: How General Data Protection Regulation will affect your organization” by Tieto)

Principles (context is key!)

- Purpose binding (only for one purpose)
- Data minimization (drop data when no longer needed for specified purpose)
- Transparency and openness (e.g., breach notifications)
- Information security (confidentiality, integrity, availability, portability)
- Accountability (internal and external auditing)

(Source: “The ABC of GDPR: How General Data Protection Regulation will affect your organization” by Tieto)

Rights of the Individual

- **Access** (a copy, *data portability*)
- **Rectify** (inaccurate or incomplete)
- **Block** (restrict processing) **and erase**
(purpose fulfilled, consent withdrawn, ...)
- **Withdraw consent** (for new data)

(Source: “The ABC of GDPR: How General Data Protection Regulation will affect your organization” by Tieto)

(Source: <https://ico.org.uk/for-organisations/guide-to-the-general-data-protection-regulation-gdpr/individual-rights/>)

Public Administrations and Research

Processing outside of EU is allowed:

- E.g., Amazon Web Services is working to be GDPR compliant

Specific to Denmark:

- Approval needed for public administrations
 - subject to change (e.g. from national to local regions, data protection officer)
- Measures should be taken so that data can be disposed or destroyed in the event of war or similar conditions

cachet

Copenhagen
Center for
Health Technology



Technical
University of
Denmark



The Capital Region
of Denmark



UNIVERSITY OF
COPENHAGEN



Privacy by Design

- Risk analysis needed to choose relevant strategies
 - Identify assets
 - Identify associated risks (likelihood / impact)
 - Implement measures for highest risks

(Source: “Privacy and Data Protection by Design — from policy to engineering” by ENISA)

Privacy by Design

- Data-oriented strategies
 - Minimize (only collect what is needed, e.g., anonymisation and pseudonyms)
 - Hide (e.g., encryption at rest/in transit, mix networks)
 - Separate (process in distributed fashion, store data separately)
 - Aggregate (information applies to multiple individuals)

(Source: “Privacy and Data Protection by Design — from policy to engineering” by ENISA)

Privacy by Design

- Process-oriented strategies
 - Inform (transparency)
 - Control (agency over data)
 - Enforce (privacy policy enforced by technical mechanisms)
 - Demonstrate (be able to prove compliance)

(Source: “Privacy and Data Protection by Design — from policy to engineering” by ENISA)