FACULTEIT
RECHT EN CRIMINOLOGIE

GENTS INSTITUUT VOOR GEZONDHEIDSRECHT

BIO-MEDICAL RESEARCH AND PRIVACY PROTECTION

THE IMPLICATIONS OF THE GDPR

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RESEARCH ON HEALTH DATA

- Essential difference between
  - Primary research (collecting data for research)
  - Secondary research (re-using clinical data)

- Difference between
  - Processing data for clinical studies
  - Processing data of clinical trial-data for other scientific purposes
  - Retrospective studies

GDPR

- Very important for both types of research
- With several exemptions in favor of scientific research

GDPR PRINCIPLES – DATA CAN ONLY BE PROCESSED

- Lawfully, fairly and in a transparent manner (***lawful basis***)
- Collected for specified, explicit and legitimate purposes and not further processed in a manner that is incompatible with those purposes (***purpose limitation***)
- Accurate and, where necessary, kept up to date (***accuracy***)

- Kept in a form which permits identification of data subject no longer than is necessary (***storage limitation***)
- In a manner that ensures appropriate security (**integrity and confidentiality)**
- In a way that demonstrates compliance (***accountability***)

SIX POSSIBLE LAWFUL BASES

- Consent of the data subject
- Performance of a contract
- Legal obligation
- Protecting vital interest of the data subject
- Task carried out in the public interest
- '*processing is necessary for the purposes of the legimate interests pursued by the controller, except when such interest are overridden by the interests of fundamental rights and freedoms of the data subject*'

DISCUSSION ABOUT CONSENT

- Is consent necessary?
- Is consent the (best) lawful basis for research?
  - Free?
  - Informed?
  - What if consent is withdrawn?

CONFUSION BETWEEN TYPES OF CONSENT

- Consent as legal basis for
  - treatment
  - or clinical trial
- Consent as legal basis for processing
  - Data necessary for diagnosis or treatment
  - Data collected during clinicial trial
  - Re-processing data for research

PRIMARY RESEARCH

- Lawful basis is generally the consent of the data subject

– Consent of the data subject means any “freely given, specific, informed and unambiguous indication of the data subject’s wishes by which he or she, by statement or by clear affirmative action, signifies agreement to the processing of personal data relating to him or her” (art. 4 GDPR)

BROAD CONSENT?

- Is complete information about the (future) purpose
  - Possible ?
  - Desirable ?

BROAD CONSENT ?

– '*It is often not possible to fully identify the purpose of personal data processing for scientific research purposes at the time of data collection. Therefore, data subjects should be allowed to give their consent to certain areas of scientific research when in keeping with recognised ethical standards for scientific research. Data subjects should have to opportunity to give their consent only to certain areas of research*' (recital 33)

- How broad ?
  - ‘research ?’
  - ‘areas of research’ ?
  - How restricted?

- Discussion about trustworthy use
  - Individual control ?
  - Collective control?

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CLINICAL TRIALS

- Opinion European Data Protection Board (23/1/19) on relation between CTR and GDPR
- EPDB: Lawful basis can be
  - ‘public interest’ (6.1.e)
  - ‘legitimate interest’ (6.1.f)
  - ‘under specific circumstances, when all conditions are met, data subjects’ explicit consent’

SECONDARY RESEARCH

- Lawfull basis is not consent, but general interest !
- Re-using clinical data seems to be an infringement of the principle of purpose limitation
- Important exemption in GDPR: "*further processing for scientific purposes shall not be considered to be incompatible with the initial purpose"* (art. 5 b)

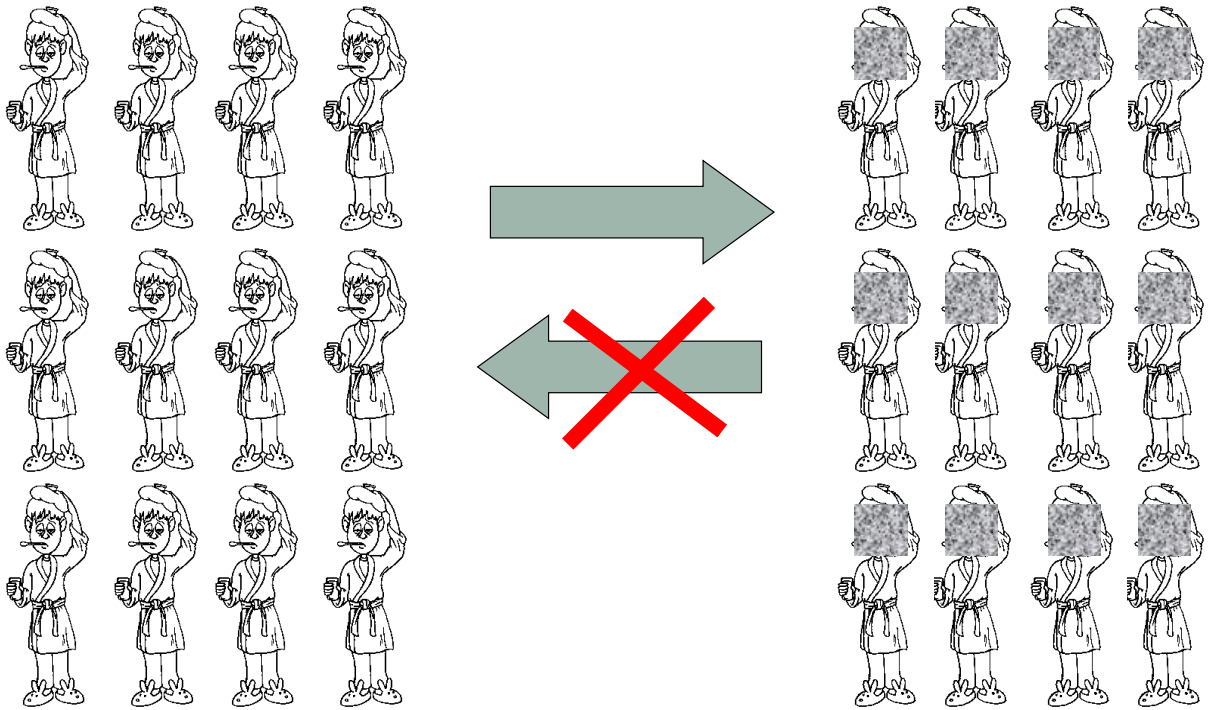
ART. 89.1 GDPR

- “Processing for scientific research purposes shall be subject to ***appropriate safeguards*** in accordance with this regulation, for the rights and freedoms of the data subject. Those safeguards shall ensure that technical and organisational measures are in place in particular in order to respect the principle.***Those measures may include pseudonymisation*** of data minimisation. provided that those purposes can be fulfilled in that manner. Where those purposes can be fulfilled by further processing which does not permit or no longer permits the identification of data subjects, those purposes shall be fulfilled in that manner”

APPROPRIATE SAFEGUARDS

- ‘Technical and organisational measures’
- Measures may include pseudonymisation
- The ongoing confusion between ‘anonymisation’ and ‘pseudonymisation’

ANONYMISATION



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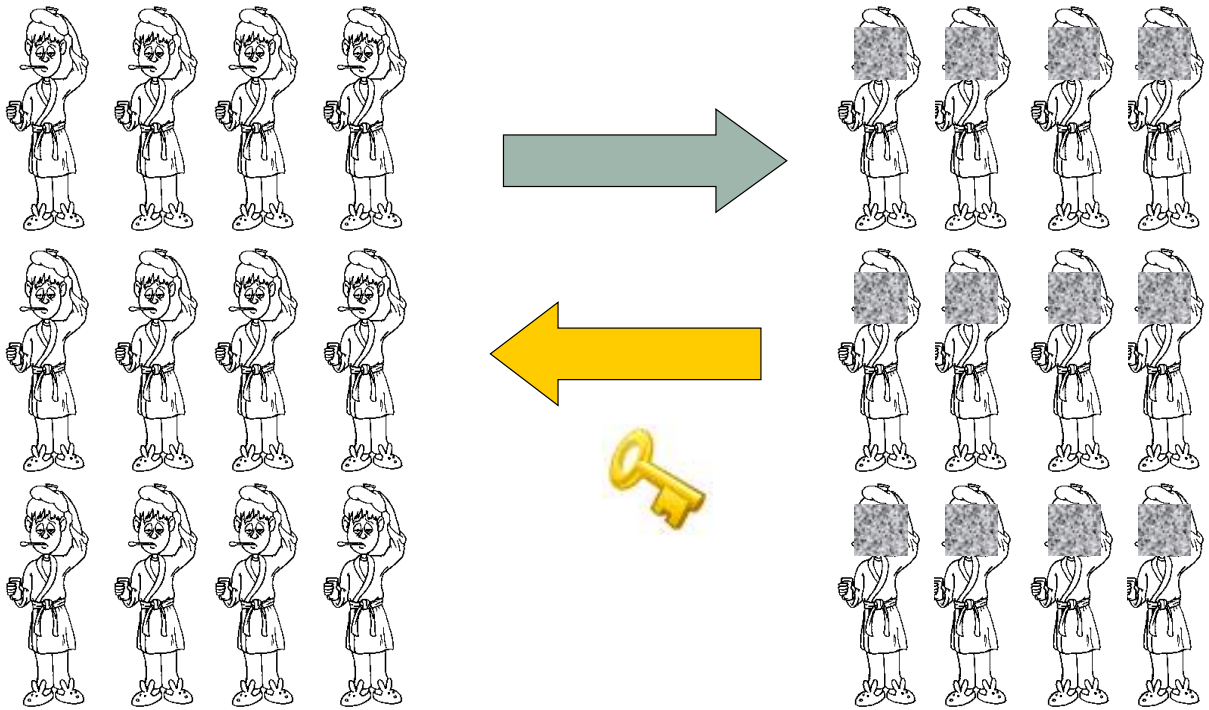
PSEUDONYMISATION



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IS ANONYMITY STILL POSSIBLE ?

- When human material (tissue, blood, bone) is stored (in bio bank) the DNA itself is an identifier
- Complete anonymity is an illusion
- Strong ‘PET’s’ can protect the privacy and make re-identification very difficult, but not impossible

DEROGATIONS ON INDIVIDUAL RIGHTS

- Art. 89.2. Union or national law can allow derogations where rights are likely to render impossible or seriously impair the achievement of the specific purposes of the research
- Rights concerned
  - Right to acces
  - Right to rectification
  - Right to restriction of processing

EXAMPLE OF NATIONAL LAW

- Belgian Privacy Law 30 july 2018 (‘Kaderwet’)
  - Implementation directive 2016/680 (police and justice-
  - ‘open’ clauses of the GDPR (ex. Age for social media)
  - Implementation of research exemption (art. 89 GDPR)

- To obtain derogations in favour of research (research exemption under 89.2 GDPR): three conditions in Belgian privacy law 2018

- (1) Contract between (initial) data controller and further processor or controller (controller of clinical data and researcher)
- (2) ‘Cascade’
  - Anonymisation
  - If research purpose cannot be reached: pseudonymisation
  - If research purpose cannot be reached: identifiable data

- Motivation for the choice in processing register, under supervision of the DPO

- (3) Moment of pseudonymisation
  - Always before further processing
  - Or via TTP

- Code of conduct with other ‘appropriate safeguards’ is possible: work in process by VLIR and RUZB

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