GDPR and health research

A ***very, very*** brief introduction

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Outline

- Wake up call
- Background of the GDPR
- Result of that background for research
- What changed because of the GDPR and what did not change
- Outlook on future discussions

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GDPR buzz & fuzz

- Bombarded with mails
  - Most of them were not necessary
  - As the legal basis for data processing was not consent
  - Consent is not the only legal basis to process personal data
    - Contract, legal obligation, vital interests, task public interest, legitimate interests of the controller
- 'we have to do this or that because of the GDPR'
  - most of that had to be done already much earlier as that was part of the existing law
- GDPR has been a WAKE UP CALL
  - Do researchers need to 'woken up' ?
- First some steps back… the context….

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General Data Protection Regulation

- *Complex* EU Regulation
- Complex because
  - Many articles and recitals, with principles and exceptions
  - Also result of a political compromise
    - Hence some texts lack even more clarity than legal texts do already in general
- Regulation
  - Directly applicable
    - Does not need to be implemented into national law
  - HOWEVER
    - Except when there is an explicit possibility for national law

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Background

- Europe had Privacy Directive 95/46/EC
  - Was not considered apt for the digital age
  - Also considering the EU Charter with fundamental rights on data protection and privacy
- In 2012 Commission proposal for a Regulation
  - The EP and Council can make amendments and a compromise needs to be reached ('trialogue')
  - EP proposed its version in 2014 (Allbregt)
    - There were about 3000 amendments, lobby from industry ('anti FB law')
    - Was much stricter for research
    - Basically abolished health research without consent
    - The 'data save lives' campaign, led by the Wellcome Trust (with patient organisations)
- Council listened ….

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Background 2

- Hence compromise negotiations…
  - Obviously not only about research….
  - Concern about small businesses
- Compromise resulted in:
  - At points rather unclear texts
  - Giving more leeway for research and leeway to national governments to regulate certain research exemptions in national law
  - Such as the exemption to informed consent
- For a full overview see:
  - http://www.medlaw.nl/nieuws/gdpr-and-research/

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Result GDPR for research

- EU did not achieve full harmonisation
- Same applies to clinical registries for 'high norms' about quality and safety of the health care system
- Yet, the national exemptions should be applied within the context of the GDPR
  - Such as by privacy by design

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What changed in general…

- The bar for consent has been set higher
  - And its consequences if consent is revoked
    - Research exception there…
- The bar for transparency has been set higher
  - Privacy statement
- Records of data processing
  - Instead of notification to national authority
- A data protection impact assessment (DPIA) for new large scale data processing of sensitive data
- Fines for not complying…
  - *Can* indeed be high
  - Subject to administrative law, proportionality test

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Changed….?

- Data security
  - All research (and health care providers) should have implemented that already
- DPO (FG in Dutch)
  - In the Netherlands was already implemented by most organisations …
- Data minimisation
  - All research should be based on a protocol
    - but what about big data research ??
- Privacy by design and by default
  - Why you are using a certain type of data always needs a defence
  - But in a research context, didn't we do that already ??
    - Certainly follows from the 2004 (!) Code of Conduct

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What did not change

- The definition of personal data
  - Identifiable = by means likely reasonably to be used
  - singling out is not personal data per se (unlike EP version)
  - Pseudonymised data can still be anonymous data
    - Marjolein will come back to that …
- Further processing for statistics or research is not incompatible with original purpose
- Several legal grounds for processing personal data, even sensitive
  - *Informed consent is 'only' one of them !!!*
- Rights of the data subject !
  - Except data portability…
  - Research exceptions

- In the Netherlands research exemptions remained the same !!
  - Actually got a clearer position

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In discussion …

- 'broad consent' (*if* consent is used, always with volunteers)
- Specific, unambiguous indication of what you want with the data (4.11)
  - For multiple purposes: consent for each of them

Yet, Recital 33 (after the negotiations, rather opaque text)

- Not always possible for fully identify purpose for scientific research…
- So consent can cover certain areas of research if in accordance with ethical standards
  - But participant should be able to narrow this down…

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What's next ….

- Further discussion on 'broad' consent
- Consent with active cohorts was always quite elaborate but could never be about specific tests or a complete list of databases to be linked with ….
  - Teaser for discussion
  - I don't believe in dynamic consent and so called 'control'
  - Both for practical and ethical reasons

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And …

- The governance of GDPR governance
- Lot still unclear
  - E.g. what means 'public interest'.
- Art. 29 WP > Eur. Data Protection Board
  - Follow the EP ideal of informational self-determination
    - Undermines solidarity
  - May be influenced by discussion in literature
    - Hence we should influence that
  - COREON statements
  - EU Code of Conduct
    - Pro research 'bias'

- And CJEU will ultimate decide

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'Take home'

- Comply
  - Not that much has changed

And

- Explain
- Influence the debate for responsible research in the public interest

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