

Today's Agenda

- Panel 1 Research: 'A Specific Processing Situation'
- Safeguards, Ethics and the Free Flow of Personal Data
- Panel 2 Secondary research – real world evidence, big data
research and biobanking
- Panel 3 Transnational transfers of personal data for research
- Panel 4 Challenges for international academic and industry
collaborations and Horizon Europe

Panel 1

Research: 'A Specific Processing Situation' *- Safeguards, Ethics and the Free Flow of Personal Data*

Moderator Jasper Bovenberg - Attorney at law

Panelists:

1. Albena Kuyumdzhieva, Programme Manager Research/Ethics Review of DG Research and Innovation; responsible for Ethics Compliance Review of H2020 programme
2. Nicolas Hamblenne, a lawyer with KOAN law firm in Brussels, specialised in privacy and data protection matters
3. Dyann Heward-Mills, a lawyer specialised in data protection and privacy matters. Dyann is the CEO of Heward-Mills, a Global DPO Office, based in London.

Panel 1 – Goal

- to help ensure continued and compliant pan European and global sharing of medical research data
- this goal threatens to be caught, not by the GDPR but by ‘GDPR Fever’

Panel 1 – Goal



UW KERK NA INVOERING VAN DE PRIVACYWETGEVING ?

Panel 1 – Goal

GDPR Fever in Church



Lindqvist case (2003)

Mrs Lindqvist was a volunteer for a church in Alseda, Sweden;

She had created a website with information for the churchgoers with details about herself and a few fellow parishioners;

‘In a mildly humorous manner’ she had mentioned that one of them had a broken foot;

She was prosecuted, in criminal proceedings, for violating the EU Directive, specifically for processing sensitive data without prior notice and without consent and transfer;

She was fined SEK 4,000,- and to pay SEK 300 to a Swedish fund to assist victims of crimes;

The European Court of Justice ‘confirmed’ the violations found by the Swedish court.

Panel 1 - Agenda & Format

- Q 1 – What are ‘Appropriate Safeguards’?
 - Input & Answers
- Q 2 – Does Research Ethics trump GDPR?
 - Input & Answers
- Q 3 - Does GDPR Implementation in Member States’ law undermine the free flow of personal data for pan EU research?
 - Input & Answers

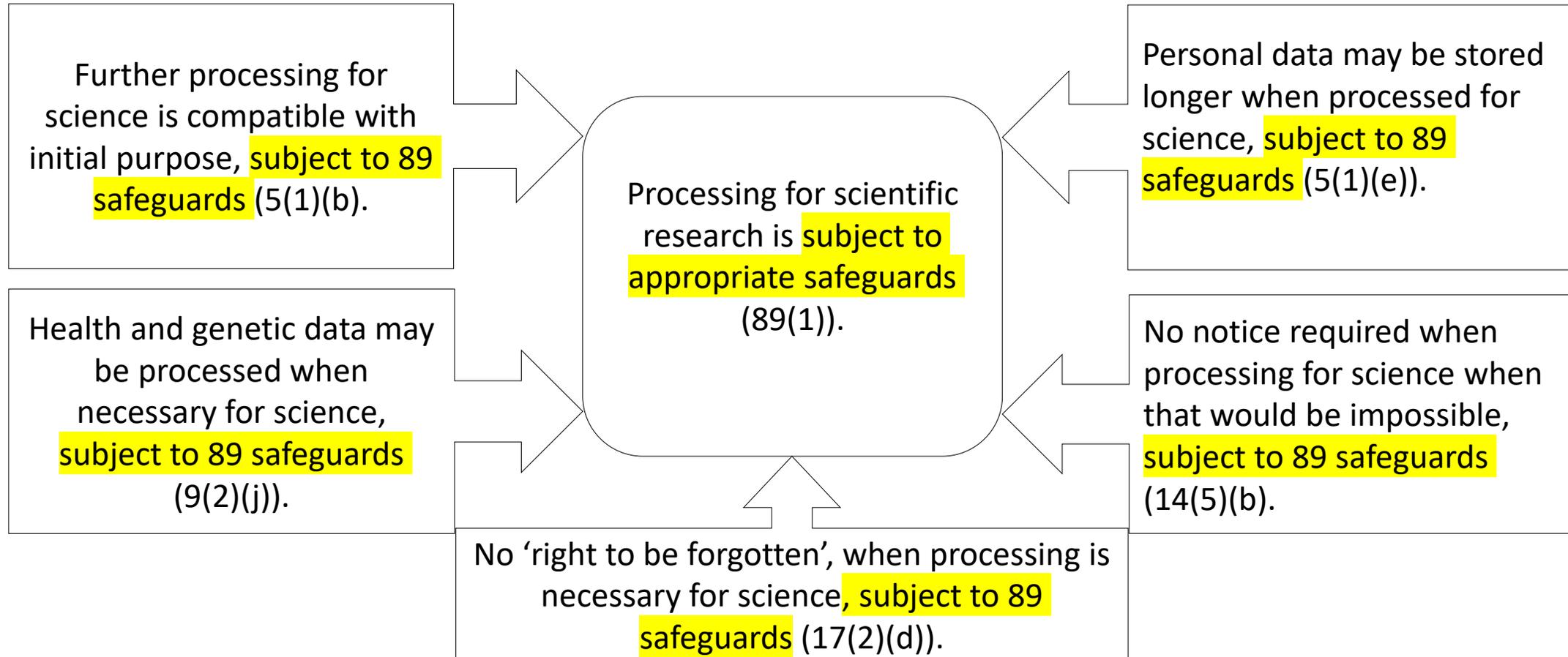
GDPR: Processing Personal Data is subject to 8 Principles



GDPR & Research

- GDPR applies to research
- Research defined broadly (e.g.):
 - technological development & demonstration,
 - fundamental research, applied research; and
 - privately funded research
- GDPR ‘promotes’ research - taking into account the Union's objective of achieving a European Research Area.
- However, GDPR considers research a ‘*specific processing situation*’

Q 1 – What are ‘Appropriate Safeguards’?



Q 2 – Does Research Ethics trump GDPR?

- The EU Partners of an international research consortium want to transfer their data to a number of collaborators outside Europe.
- The consortium is GDPR compliant, including a mechanism for transfer of the data
- Yet, the Ethical Review Board says no. They block the transfer of the data, because “ethical standards” require informed consent

Q 3 - Does GDPR Implementation in Member States' law undermine the free flow of personal data for pan EU research?

- The goal of the GDPR is twofold:
 1. to ensure a consistent and high level of data protection; and
 2. to remove the obstacles to flows of personal data within the Union
- GDPR provides a 'margin of manoeuvre' for Member States
 - Member States may introduce further conditions, e.g. for processing genetic data, biometric data or data concerning health.
- GDPR also requires a national law when, e.g., invoking some GDPR research provisions such as Article 9(2)(j) (processing is necessary for research)

Q 3 – Does GDPR Implementation in Member States' law undermine the free flow of personal data for pan EU research? And if so, how to address this?

Declaration for delivering cross-border access to **genomic database**



1 million **genomes accessible** in the EU by 2022

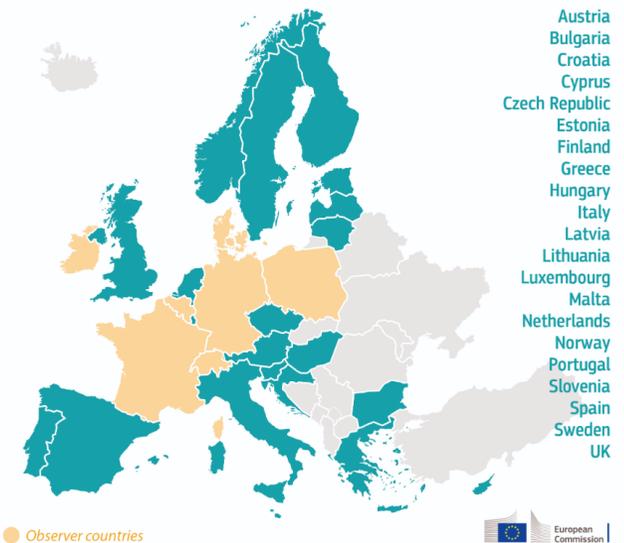


Linking access to existing and future genomic database across the EU



Providing a sufficient scale for **new clinically impactful** associations in research

EU countries agreed to cooperate in linking genomic data across borders



**Q 4 does the GDPR block
or enable the use of AI in
health research?**