

# Data sharing between countries

Heidi Beate Bentzen

Researcher, Centre for Medical Ethics, University of Oslo

Nordic Biobank Conference 2022

# Conflict of interest

Relevant funding source:



## **Responsible Open Science in Europe**

Funded under the European Union's Horizon 2020 research and innovation programme grant agreement No. 101006430.

Funding also received from the Cancer Registry of Norway.

Collaborations on this topic with ALLEA, EASAC, FEAM, and NSHG-PM.

# EU aim: Strengthened scientific and technological bases

## GDPR objective: Protection and flow



# Data transfer from the EEA to outside the EEA: A three tiered system

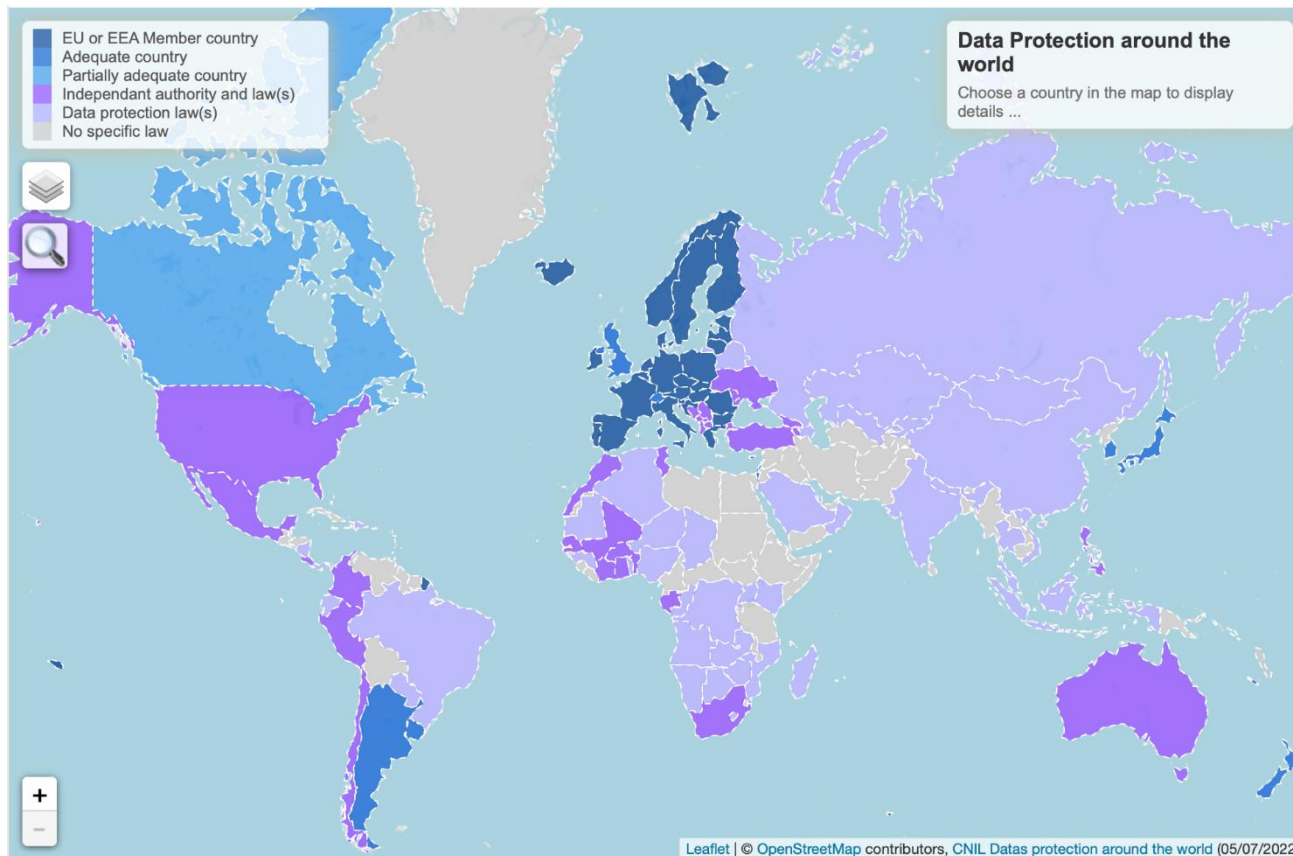
- Red light: Derogations for specific situations
- Yellow light: Appropriate safeguards
- Green light: Adequacy decision



# Best option: Adequacy









## Reports of Cases

### JUDGMENT OF THE COURT (Grand Chamber)

16 July 2020\*

(Reference for a preliminary ruling — Protection of individuals with regard to the processing of personal data — Charter of Fundamental Rights of the European Union — Articles 7, 8 and 47 — Regulation (EU) 2016/679 — Article 2(2) — Scope — Transfers of personal data to third countries for commercial purposes — Article 45 — Commission adequacy decision — Article 46 — Transfers subject to appropriate safeguards — Article 58 — Powers of the supervisory authorities — Processing of the data transferred by the public authorities of a third country for national security purposes — Assessment of the adequacy of the level of protection in the third country — Decision 2010/87/EU — Protective standard clauses on the transfer of personal data to third countries — Suitable safeguards provided by the data controller — Validity — Implementing Decision (EU) 2016/1250 — Adequacy of the protection provided by the EU-US Privacy Shield — Validity — Complaint by a natural person whose data was transferred from the European Union to the United States)

In Case C-311/18,

REQUEST for a preliminary ruling under Article 267 TFEU from the High Court (Ireland), made by decision of 4 May 2018, received at the Court on 9 May 2018, in the proceedings

**Data Protection Commissioner**

v

**Facebook Ireland Ltd,**

**Maximillian Schrems,**

intervening parties:

**The United States of America,**

**Electronic Privacy Information Centre,**

**BSA Business Software Alliance Inc.,**

**Digitaleurope,**



# Cloud computing



[Forside](#) > [Aktuelt](#) > [Setter arbeidet med Helseanalyseplattformen på pause](#)

## Setter arbeidet med Helseanalyseplattformen på pause

Direktoratet for e-helse har besluttet å sette utviklingen av Helseanalyseplattformen på pause. Bakgrunnen er i hovedsak juridiske utfordringer som følge av Schrems II-dommen. Dette betyr



# Cloud computing



Administration Priorities

BRIEFING ROOM

## United States and European Commission Joint Statement on Trans-Atlantic Data Privacy Framework

MARCH 25, 2022 • STATEMENTS AND RELEASES

The United States and the European Commission announce that they have agreed in principle on a new Trans-Atlantic Data Privacy Framework, which will foster trans-Atlantic data flows and address the concerns raised by the Court of Justice of the European Union in the *Schrems II* decision of July 2020.

NORDIC  
**Biobank  
Conference**



The European Commission and the United States reached an agreement in principle for a **Trans-Atlantic Data Privacy Framework**.

### Key principles

- ◆ Based on the new framework, **data will be able to flow freely and safely** between the EU and participating U.S. companies
- ◆ A new set of rules and **binding safeguards to limit access to data** by U.S. intelligence authorities to what is **necessary and proportionate** to protect national security; U.S. intelligence agencies will adopt procedures to ensure effective oversight of new privacy and civil liberties standards
- ◆ **A new two-tier redress system** to investigate and resolve complaints of Europeans on access of data by U.S. Intelligence authorities, which includes a **Data Protection Review Court**
- ◆ **Strong obligations for companies** processing data transferred from the EU, which will continue to include the requirement to self-certify their adherence to the Principles through the U.S. Department of Commerce
- ◆ **Specific monitoring and review mechanisms**



# Cloud computing



Max Schrems   
@maxschrems

...

What you read and hear does however point more at another "lipstick on a pig" approach -- that will we slaughtered in Luxemburg in no time.. 😞 (3)

[#SchremsIII](#)

[Oversett](#) [tweeten](#)



12:48 p.m. · 24. mar. 2022 · Twitter for Android

# Second best option: Appropriate safeguard



*Article 46*

**Transfers subject to appropriate safeguards**

1. In the absence of a decision pursuant to Article 45(3), a controller or processor may transfer personal data to a third country or an international organisation only if the controller or processor has provided appropriate safeguards, and on condition that enforceable data subject rights and effective legal remedies for data subjects are available.
2. The appropriate safeguards referred to in paragraph 1 may be provided for, without requiring any specific authorisation from a supervisory authority, by:
  - (a) a legally binding and enforceable instrument between public authorities or bodies;
  - (b) binding corporate rules in accordance with Article 47;
  - (c) standard data protection clauses adopted by the Commission in accordance with the examination procedure referred to in Article 93(2);
  - (d) standard data protection clauses adopted by a supervisory authority and approved by the Commission pursuant to the examination procedure referred to in Article 93(2);
  - (e) an approved code of conduct pursuant to Article 40 together with binding and enforceable commitments of the controller or processor in the third country to apply the appropriate safeguards, including as regards data subjects' rights; or
  - (f) an approved certification mechanism pursuant to Article 42 together with binding and enforceable commitments of the controller or processor in the third country to apply the appropriate safeguards, including as regards data subjects' rights.
3. Subject to the authorisation from the competent supervisory authority, the appropriate safeguards referred to in paragraph 1 may also be provided for, in particular, by:
  - (a) contractual clauses between the controller or processor and the controller, processor or the recipient of the personal data in the third country or international organisation; or
  - (b) provisions to be inserted into administrative arrangements between public authorities or bodies which include enforceable and effective data subject rights.

*Article 46*

**Transfers subject to appropriate safeguards**

1. In the absence of a decision pursuant to Article 45(3), a controller or processor may transfer personal data to a third country or an international organisation only if the controller or processor has provided appropriate safeguards, and on condition that enforceable data subject rights and effective legal remedies for data subjects are available.

2. The appropriate safeguards referred to in paragraph 1 may be provided for, without requiring any specific authorisation from a supervisory authority, by:

- (a) a legally binding and enforceable instrument between public authorities or bodies;
- (b) binding corporate rules in accordance with Article 47;
- (c) standard data protection clauses adopted by the Commission in accordance with the examination procedure referred to in Article 93(2);
- (d) standard data protection clauses adopted by a supervisory authority and approved by the Commission pursuant to the examination procedure referred to in Article 93(2);
- (e) an approved code of conduct pursuant to Article 40 together with binding and enforceable commitments of the controller or processor in the third country to apply the appropriate safeguards, including as regards data subjects' rights; or
- (f) an approved certification mechanism pursuant to Article 42 together with binding and enforceable commitments of the controller or processor in the third country to apply the appropriate safeguards, including as regards data subjects' rights.

3. Subject to the authorisation from the competent supervisory authority, the appropriate safeguards referred to in paragraph 1 may also be provided for, in particular, by:

- (a) contractual clauses between the controller or processor and the controller, processor or the recipient of the personal data in the third country or international organisation; or
- (b) provisions to be inserted into administrative arrangements between public authorities or bodies which include enforceable and effective data subject rights.


Lack of guidelines



# Statutory conflicts



# Standard Contractual Clauses



European  
Commission

EN English

[Home](#) > [Law](#) > [Law by topic](#) > [Data protection](#) > [International dimension of data protection](#) > [Standard Contractual Clauses \(SCC\)](#)

## Standard Contractual Clauses (SCC)

Standard contractual clauses for data transfers between EU and non-EU countries.

According to the General Data Protection Regulation (GDPR), contractual clauses ensuring appropriate data protection safeguards can be used as a ground for data transfers from the EU to third countries. This includes model contract clauses – so-called standard contractual clauses (SCCs) – that have been “pre-approved” by the European Commission.

On [4 June 2021](#), the Commission issued modernised standard contractual clauses under the GDPR for data transfers from controllers or processors in the EU/EEA (or otherwise subject to the GDPR) to controllers or processors established outside the EU/EEA (and not subject to the GDPR):

These modernised SCCs will replace the three sets of SCCs that were adopted under the previous Data Protection Directive 95/46.

### Documents

04 JUNE 2021 | JUSTICE AND CONSUMERS

[Standard contractual clauses for international transfers](#)

Modernised standard contractual clauses for the transfer of personal data to third countries

# U.S. Federal Institutions: Sovereign immunity



## *Article 46*

### **Transfers subject to appropriate safeguards**

1. In the absence of a decision pursuant to Article 45(3), a controller or processor may transfer personal data to a third country or an international organisation only if the controller or processor has provided appropriate safeguards, and on condition that enforceable data subject rights and effective legal remedies for data subjects are available.

# Sovereign immunity: Expand waiver?

## nature medicine

[Explore content](#) ▾ [About the journal](#) ▾ [Publish with us](#) ▾

[nature](#) > [nature medicine](#) > [comment](#) > article

Comment | [Published: 02 August 2021](#)

### **Remove obstacles to sharing health data with researchers outside of the European Union**

[Heidi Beate Bentzen](#), [Rosa Castro](#) ✉, [Robin Fears](#), [George Griffin](#), [Volker ter Meulen](#) & [Giske Ursin](#)

[Nature Medicine](#) **27**, 1329–1333 (2021) | [Cite this article](#)

# Supplementary measures



**Recommendations 01/2020 on measures that supplement transfer tools to ensure compliance with the EU level of protection of personal data**

**Version 2.0**

**Adopted on 18 June 2021**



**NSHG-PM**

Nordic Society of Human Genetics and Precision Medicine

21 December 2020

## Executive Committee

### President

**Kári Stefánsson**  
Iceland

### Vice-President

**Paul W. Franks**  
Sweden

### Treasurer

**Søren Brunak**  
Denmark

## Council

**Ole A. Andreassen**  
Norway

**Andres Metspalu**  
Estonia

**Lili Milani**  
Estonia

**Pål R. Njølstad**  
Norway

**Comments on EDPB Recommendations 01/2020 on measures that supplement transfer tools to ensure compliance with the EU level of protection of personal data**

**In recognition of EDPB Recommendations 01/2020**, the legal working group of the Nordic Society of Human Genetics and Precision Medicine (NSHG-PM) respectfully submits comments for technical, organizational, and legal supplementary measures to achieve an essentially equivalent standard of protection when transferring personal data for medical scientific research to collaborators outside the EEA.

Our aim is to ensure that medical scientific research will still be feasible to conduct and that research participants' fundamental rights will be respected in the process. Regrettably, we do not believe that the Recommendations in the current version achieve this aim.

While a goal of the Recommendations may be to ensure that research participants' fundamental rights will be respected, in their current version, the Recommendations will hinder a large proportion of medical scientific research. Hence, we respectfully submit suggestions for a manner in which



# Derogations for specific situations – Use with caution



# Safety valve derogation



# Technical solutions

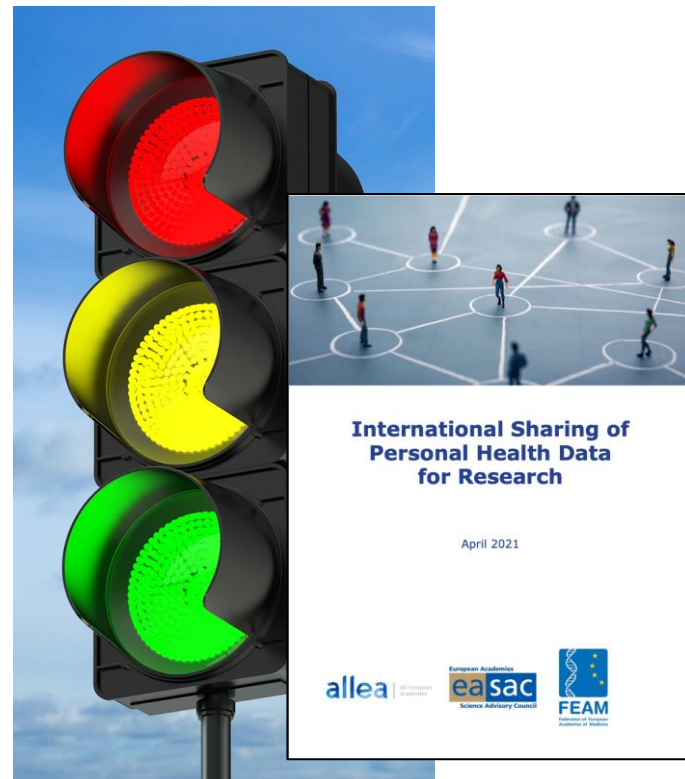


# Data transfer from the EEA to outside the EEA: A three tiered system

- Red light: Derogations for specific situations

- 
- Yellow light: Appropriate safeguards

- Green light: Adequacy decision



# Further reading



The screenshot shows the top navigation bar of the Annual Reviews website with links for JOURNALS A-Z, JOURNAL INFO, and PRICING & SUBSCRIPTION. Below the navigation bar is a breadcrumb trail: Home / Annual Review of Biomedical Data Science / Volume 5, 2022 / Bentzen, pp 233-250. The main title of the article is 'Exchange of Human Data Across International Boundaries'. Below the title, it specifies 'Annual Review of Biomedical Data Science', 'Vol. 5:233-250 (Volume publication date August 2022)', 'First published as a Review in Advance on May 10, 2022', and the DOI link 'https://doi.org/10.1146/annurev-biodatasci-122220-110811'. The author's name, 'Heidi Beate Bentzen', is listed at the bottom of the article preview.

**ANNUAL REVIEWS**

JOURNALS A-Z JOURNAL INFO PRICING & SUBSCRIPTION

Home / Annual Review of Biomedical Data Science / Volume 5, 2022 / Bentzen, pp 233-250

## Exchange of Human Data Across International Boundaries

**Annual Review of Biomedical Data Science**  
Vol. 5:233-250 (Volume publication date August 2022)  
First published as a Review in Advance on May 10, 2022  
<https://doi.org/10.1146/annurev-biodatasci-122220-110811>

**Heidi Beate Bentzen**

<http://www.annualreviews.org/eprint/YF4XDV3BBVJHIIMEIVYS/full/10.1146/annurev-biodatasci-122220-110811>



# Thank you!

Heidi Beate Bentzen

[h.b.bentzen@medisin.uio.no](mailto:h.b.bentzen@medisin.uio.no)

@HeidiBBentzen