THE UNIVERSITY *of* EDINBURGH

Edinburgh Research Explorer

Raising standards for global data-sharing

Citation for published version:

Dove, ES, Chen, J & Loideain, NN 2021, 'Raising standards for global data-sharing', *Science*, vol. 371, no. 6525, pp. 133-134. <https://doi.org/10.1126/science.abf4286>

Digital Object Identifier (DOI):

[10.1126/science.abf4286](https://doi.org/10.1126/science.abf4286)

Link:

[Link to publication record in Edinburgh Research Explorer](#)

Document Version:

Peer reviewed version

Published In:

Science

Publisher Rights Statement:

This is the author's version of the work. It is posted here by permission of the AAAS for personal use, not for redistribution. The definitive version was published in *Science* on Volume 371, Issue 6525, 8 January 2021, DOI: [10.1126/science.abf4286](https://doi.org/10.1126/science.abf4286)

General rights

Copyright for the publications made accessible via the Edinburgh Research Explorer is retained by the author(s) and / or other copyright owners and it is a condition of accessing these publications that users recognise and abide by the legal requirements associated with these rights.

Take down policy

The University of Edinburgh has made every reasonable effort to ensure that Edinburgh Research Explorer content complies with UK legislation. If you believe that the public display of this file breaches copyright please contact openaccess@ed.ac.uk providing details, and we will remove access to the work immediately and investigate your claim.

Raising standards for global data-sharing

In their Policy Forum “How to fix the GDPR’s frustration of global biomedical research” (2 October 2020, p. 40), J. Bovenberg *et al.* argue that the biomedical research community has struggled to share data outside the European Union as a result of the EU’s General Data Protection Regulation (GDPR), which strictly limits the international transfer of personal data. However, they do not acknowledge the law’s flexibility, and their solutions fail to recognize the importance of multilateral efforts to raise standards for global data-sharing.

Bovenberg *et al.* express concern about the thwarting of “critical data flows” in biomedical research. However, the limited number of critical commentaries (1,2) and registered complaints (3) indicate that hindered data exchange may not be a substantial global problem. Moreover, the authors concede that during the COVID-19 pandemic, data transfers remain ongoing because transfers “necessary for important reasons of public interest” are already provided in the law [(4), Article 49(1)(d)]. The European Data Protection Board (EDPB) has cautioned that transfers according to this derogation shall not become the rule in practice (5), but this conditional support for international COVID-19 data sharing shows that the law already provides suitable flexibility. This flexibility also shows the EDPB’s recognition of the pressing social need that biomedical research represents for the global research community during the COVID-19 pandemic, while also seeking to ensure that this remains the exception and not the beginning of a normalized practice.

Bovenberg *et al.* contend that pseudonymized data should not be considered personal data in the hands of an entity that does not possess the key needed for re-identification. This proposal runs against well-established guidance in EU member states such as Ireland (6) and Germany (7), and it does not take into account the cases in which identifiers remain attached to transferred biomedical data or in which data could be identified without a key.

Bovenberg *et al.* also neglect to state that the GDPR has special principles and safeguards for particularly sensitive re-identifiable data, not just for the protection of privacy but also for the security and integrity of health research data—aims that align with all high-quality scientific research. Respecting these standards (both technical and organizational) is fundamental to ensuring better data security and accuracy in the transferring of huge datasets of sensitive health data that are essential to global collaboration [(4), Articles 5 and 9, Recitals 53 and 54, and (8)]. Thus, these rules should not be subject to exemptions, which would result from not classifying pseudonymized data as personal data.

The purpose of the GDPR’s strict rules is to ensure that when personal data are transferred to non-EU countries, the level of protection ensured in the European Union is not undermined. The EU’s Court of Justice decisions (9, 10) make it clear that ensuring an adequate level of protection in non-EU countries, especially independent oversight and judicial remedies—which the Court found lacking in the United States—is a matter of fundamental rights. This discrepancy is an opportunity for non-EU countries, including the United States, to raise their data protection standards to the level of the European Union’s, not for the European Union to decrease its own standards in a regulatory race to the bottom. We encourage research organizations and country delegations to work with the European Commission, national data protection authorities, and the EDPB to craft interoperable rules on data sharing applicable for biomedical research in ways that do not undermine fundamental rights owed to data subjects.

Edward S. Dove^{1*}, Jiahong Chen², Nóra Ni Loideain³

¹School of Law, University of Edinburgh, Edinburgh, UK. ²Horizon Digital Economy Research, University of Nottingham, Nottingham, UK. ³Institute of Advanced Legal Studies, School of Advanced Study, University of London, London, UK.

*Corresponding author.

Email: edward.dove@ed.ac.uk

REFERENCES AND NOTES

1. R. Eiss, *Nature* 584, 498 (2020).
2. R. Becker *et al.*, *J. Med. Internet Res.* 22, e19799 (2020).
3. A. Jelinek, EDPB response letter to Mark W. Libby, Chargé d’Affaires, United States Mission to the European Union (2020); https://edpb.europa.eu/sites/edpb/files/files/file1/edpb_letter_out2020-0029_usmission_covid19.pdf.
4. GDPR (2016); <https://gdpr-info.eu/>.
5. EDPB, “Guidelines 03/2020 on the processing of data concerning health for the purpose of scientific research in the context of the COVID-19 outbreak” (2020).
6. Data Protection Commission, “Guidance on Anonymisation and Pseudonymisation” (2019); www.dataprotection.ie/sites/default/files/uploads/2019-06/190614%20Anonymisation%20and%20Pseudonymisation.pdf.
7. German Federal Ministry of the Interior, Building and Community, “Draft for a Code of Conduct on the use of GDPR compliant pseudonymisation” (2019); www.gdd.de/downloads/aktuelles/whitepaper/Data_Protection_Focus_Group-Draft_CoC_Pseudonymisation_V1.0.pdf.
8. D. Anderson *et al.*, *Int. Data Privacy L.* 10, 180 (2020).
9. Case C-362/14 *Maximilian Schrems v. Data Protection Commissioner* (Court of Justice of the EU, 2015).
10. Case C-311/18 *Data Protection Commissioner v. Facebook Ireland Limited and Maximilian Schrems* (Court of Justice of the EU, 2020).