Nicol, D., Eckstein, L., Bentzen, H.B., Borry, P., Burgess, M., Burke, W., Chalmers, D., Cho, M., Dove, E., Fullerton, S., Ida, R., Kato, K., Kaye, J., Koenig, B., Manson, S., McGrail, K., Meslin, E., O'Doherty, K., Prainsack, B., Shabani, M., Tabor, H., Thorogood, A., de Vries, J. (2019). Consent insufficient for data release. *SCIENCE*, *364* (6439), 445-446. doi: 10.1126/science.aax0892

Consent insufficient for data release

In their Policy Forum "Toward unrestricted use of public genomic data" (25 January, p. 350), R. I. Amann *et al.* argue that once data has been cleared for release to the public domain by institutions, it should be open for use without further restrictions. However, they neglect the key point that researchers and their institutions are entrusted by research participants, funders, and others with weighing the pros and cons of public data release. By suggesting that informed consent can provide a straightforward path to data release, they overlook evidence that once people understand their options, only a little more than half opt for open data sharing, and some refuse data sharing altogether (*1*, *2*).

This evidence further shows that some research participants have concerns that uses of their data might not fit with their norms or values or might disadvantage certain populations. Despite their openness to wide use, they do not think ethics review and informed consent is sufficient to remove restrictions on the release of sensitive human data. Simply put, informed consent is a necessary, but far from sufficient condition for data sharing (*3*, *4*).

Equally important, Amann *et al.*'s proposal for data sharing through open access databases does not reflect funders' policies. Rather, funders expect and, in some cases, mandate that researchers adopt specific organizational measures to safeguard personal data. For example, the National Institutes of Health (NIH) policy on Genomic Data Sharing explicitly requires that data generators develop genomic data sharing plans and data users submit their requests to data access committees for review (*5*). The imperative for adequate data governance has also been stressed by other major funding agencies, such as the Wellcome Trust Expert Advisory Group on Data Access (*6*).

Admittedly, poorly designed regulation can stifle legitimate genomic data sharing that promotes the public good. Regulatory frameworks do, however, serve critical purposes, including ensuring consideration of the intricate ethical, legal, social, and political concerns inherent in many aspects of science, including genomics. Amann *et al.*'s uncritical use of the notion of "openness" suggests that once data has been made open, its use is unaffected by structural issues such as the unequal distribution of power and influence. This is particularly problematic in cases of for-profit enterprises that are not accountable to the public (*7*). Although Amann *et al.*'s suggestions seem emancipatory and respectful of ethical concerns, their proposal overlooks the wider political economy in which data use is embedded and conflates ethics with a rather formulaic adherence to legal and institutional guidelines and consent forms.

This complex challenge cannot be solved with a single model for data sharing governance. The currently favored model of controlled-access data sharing adopted by the NIH and others is far from perfect (*8*). Better alternatives are emerging, such as the Global Alliance for Genomics Health's Beacon federated model for data sharing (*9*). We need approaches to data sharing that address, on a case by case basis, how public release of data affects distribution of burdens and benefits across and within populations.

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REFERENCES AND NOTES

1. A. L. McGuire *et al.*, *Genet. Med*. **13**, 948 (2011).
2. N. Shah *et al.*, *Eur. J. Hum. Genet*. 10.1038/s41431-019-0344-2 (2019).
3. J. Teng *et al.*, *Intl. J. Pop. Data Sci.* **3**, 364 (2018).
4. R. E. McWhirter *et al.*, *J. Pers. Med*. **4**, 459 (2014).
5. NIH, NIH GDS Policies (https://osp.od.nih.gov/scientific-sharing/policies/).
6. Expert Advisory Group on Data Access, "Governance of data access" (2015); https://wellcome.ac.uk/sites/default/files/governance-of-data-access-eagda-jun15.pdf.
7. S. Zuboff, *The Age of Surveillance Capitalism: The Fight for the Future at the New Frontier of Power* (PublicAffairs, 2019).
8. D Mascalzoni *et al.*, *Ann. Intern. Med.* **170**, 332 (2019).
9. The Global Alliance for Genomics and Health, *Science* **352**, 1278 (2016).

10.1126/science.aax0892