

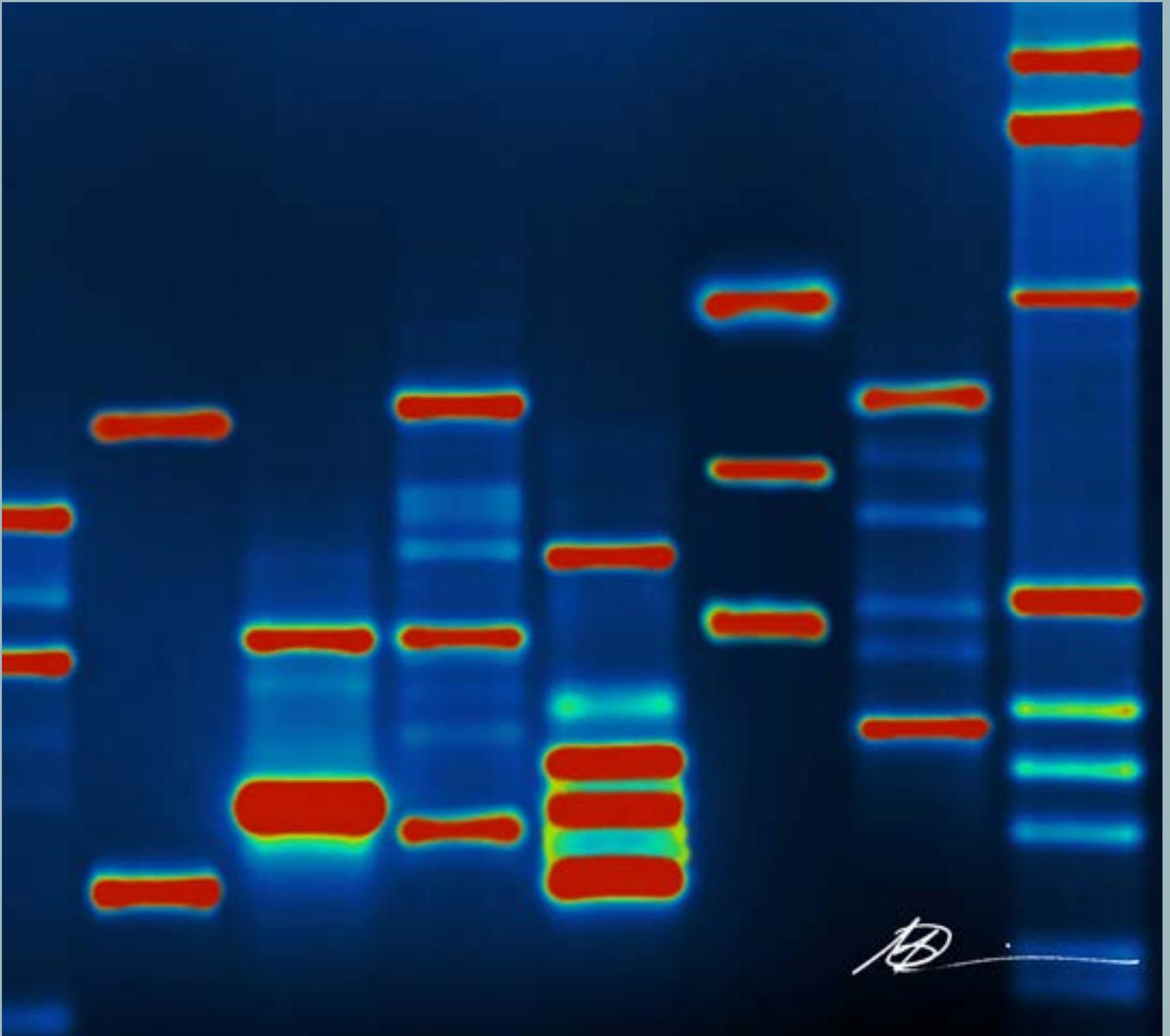


THE UNIVERSITY of EDINBURGH
Edinburgh Law School



Does data ownership hinder biomedical research?

Liminal Spaces Policy Brief



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The concept of ‘my data’ is important: notions of reward, opportunity, control, and safeguarding establish legitimate, potentially competing ‘ownership’ interests in data. In particular, this research raises serious questions about the long-term effectiveness of an open access ideology that fails to take account of these subtleties.

The research underpinning this policy brief was commissioned and funded by Wellcome’s Expert Advisory Group on Data Access (EAGDA). The impetus for the research emerged from the experiences of Wellcome as a funder that - in discussions around the use, reuse and sharing of health data in research - terminology was frequently used in relation to the ‘ownership’ of data sets. Anecdotally this was in the context of ownership acting as a barrier to sharing, and serving to restrict access. A 2017 joint report by the British Academy and the Royal Society on data management and use,¹ also recognises ownership as one of a number of ‘significant tensions’² inherent in how we use data. The report suggests that the meaning of ownership has shifted and continues to do so, and that it is a concept under ‘unprecedented strain’.³

The findings from the commissioned research are published open access in the *Journal of Law and the Biosciences* - doi:10.1093/jlb/ljaa068. The research findings speak directly to how funders and data custodians can better tailor existing and potential data sharing initiatives to perspectives and behaviors.

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sharing behaviors and expectations under a rubric of data stewardship.

Who owns data in law?

The law provides neither a straightforward nor comprehensive account of the role that ownership plays in health data sharing. Raw data, per se, are **not** subject to property law in a strict legal sense.

It is common to hear people talk about “my data” or “their data” when referring to personal data. This is not surprising: we tend to want to possess things that we value to the exclusion of the whole world (which is the essence of a property right). However, formally the law does not create a property relationship in that sense between an individual and personal data that “relate” to them. However, when those data are gathered and then processed in systematic ways, they can then become the subject of intellectual property - ‘owned’ by the person who has invested the human intellect to make the systematic processing of the data. So, in the hands of, say, the patient, there is no property (and the protection of the patient’s data is through human rights and data protection law), but the hospital and doctors that create a dataset and analyse the patient data may well have intellectual property rights - copyright and database rights - in the structured, processed data.

Thus, while both data protection and IP law may be engaged by health data sharing, the effect of these legal frameworks – in terms of how they are understood by stakeholders and impact upon data sharing practices – is far from clear. The law alone cannot account for the persistence of notions of ownership

in relation to health data; and the project therefore undertook empirical work with researchers and other stakeholders in the biomedical sphere to tease out participants’ understandings of the claims over data and the possible relationships between data and claims to ownership.

‘My data’: the enduring appeal of this story

The research found that to discount references to ‘my data’ is to fail to take into account the different ways in which stakeholders use and understand their relationships to data, and indeed the term ‘ownership’ more widely. The research shows that there is a range of perceptions of legitimate interests in data sharing. A major concern is about the protection of the rights and interests of data subjects. The participants acknowledged the obligations owed to those to whom the personal data relate. This meta-obligation reaches across data ecosystems and through data sharing agreements. Moreover, the specific transactional obligations that are then imposed in any given data sharing agreement are undoubtedly seen as barriers to data sharing, but they were not often expressed as a negative barrier; data protection and privacy were expressed as necessary barriers - as ‘positive barriers’ in data sharing - positive in that they concerned with demonstrating respect and trustworthiness and in building confidence in data sharing.

The research also demonstrated how appeals to ownership might be based in a desire for due recognition for work done on or with biomedical data, including building datasets for future research use. Indeed, in the entire biomedical

enterprise multiple actors and tasks are involved and might include: individuals donating data; researchers working on, curating and aggregating data; and/ or researchers seeking access to data. Revealing this complexity under the single umbrella term of 'my data' suggests that there may be competing stories towards and around data sharing, depending on the actors involved and the tasks they are undertaking.

A further aspect of provenance is the quality of the data. Participants indicated that a barrier to data sharing was a concern about the quality of data being received, and about what would be done with data when shared. This was again a concern to protect legitimate interests - here it was the interests of the public in maintaining high standards and quality in science. There is a reluctance in the community to share where there is no guarantee of quality. One key aspect of this that was discussed is the cost of properly curating data.

Few of the participants talked directly about the commercial, monetary value of data. When it was raised, it was in the context of data generated in hospitals, and was part of a broader understanding of the (need for) commercial considerations in that setting. However, many participants spoke about other rewards for the labor associated with data. Primarily, this was articulated in relation to publications.

Put simply: 'ownership' does not mean one static thing to all actors who use the term. This research captures this and reveals more of what is behind the label and what this might mean in terms of future policy and data sharing practice. For many, appeals to ownership are as much – if not more - about protecting and safeguarding certain interests in data, rather than a formal legal claim to property per se.

Data Stewardship: policy recommendations

These findings have a number of implications for data governance more widely. The work showed that there are barriers to data sharing, certainly, but that there are also legitimate barriers to data sharing, and the governance structures created to develop data sharing have to recognise these. It was particularly interesting to see how the language

of 'stewardship', unlike 'ownership', has traction.

The starting point of the research was a concern from EAGDA that the concept of ownership might be creating barriers to data sharing that in turn create a deleterious effect on research in vital (health) areas. Therefore, it is appropriate to conclude with six very practical

suggestions that we see as coming out of our research alongside the answer that, yes, there are ownership-like issues that can create barriers to data sharing – but these can also promote the legitimate ends of protecting participants in research, ensuring data quality and provenance, and rewarding researchers for their contributions.

Policy Recommendations

- **The creation of metadata and the appropriate management of data for effective and robust sharing costs time and effort, and funders must recognise this in the resources they make available to research projects.** Whereas some funders include resources to support the management of data (particularly the creation of metadata), the funding to create high quality data was inconsistent. This was at odds with the increasing message from funders for data sharing and open access. Data infrastructure and data access go hand-in-hand and must be funded appropriately.
- **Funders can lead in generating the infrastructures for data sharing.** There is a strong argument that effective data sharing and open access hangs on harmonisation and shared standards in data curation. There is a need for central investment in, for example, data hubs (both facilities and software innovation) and federated data systems to facilitate data sharing and open access, while recognising the different producer-user and funder-steward perspectives.
- **The effort of data creation and data analysis merits recognition for those who expend the effort.** Data generators and data holders 'own' the data on the basis that the creation of the data set, and particularly the ordering of its metadata, is highly resource-intensive, and this must be recognised. Avenues for recognition of data creation are emerging (e.g. in journals, research audits and academic performance reviews) but these are also inconsistent. Funders can push for this effective recognition.
- **Researchers should be given an appropriate time to generate original dissemination of their work.** Open access, whilst an appropriate requirement for stewardship in public spending and concerns about veracity and replication, can be at odds with the researcher's need for time to analyse and publish data. Some funders and data sharing agreements allow for a period whereby researchers have an exclusive right of "first publication" from their research. This practice is supported by this research, in that many researchers identify as 'owning' the data in that they have an expectation of a right to first publication of results that flow from their analysis and work on the data. Accordingly, this should become standard practice in funding agreements and to encourage longer-term data sharing.
- **The "open access" agenda requires careful rethinking to accommodate the range of stakeholder expectations and attitudes.** The opinions and experiences expressed by the participants in this research suggest that there are alternative versions of data sharing that may well be as legitimate as the current blanket open access agenda.
- **Funders can play a greater role in ensuring that there is fuller accountability in data sharing agreements, particularly through robust enforcement of agreements.**

References

¹ The Royal Society and The British Academy, *Data Management and Use: Governance in the 21st Century*, (2017), <https://royalsociety.org/-/media/policy/projects/data-governance/data-management-governance.pdf> (accessed 15.9.2019).

² Id. The Royal Society and The British Academy p.6

³ Id. The Royal Society and The British Academy p.29



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About the Mason Institute

This research was carried out in association with the J Kenyon Mason Institute for Medicine, Life Sciences and the Law, based at the University of Edinburgh and located within Edinburgh Law School. The Mason Institute serves as an interdisciplinary research network, aimed at investigating the interface between medicine, life sciences and the law in relation to medical and bioethical developments on a national and global scale.

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