



LEARNING FROM A DECADE OF EXPERIENCE:

WHAT MAKES GOOD GOVERNANCE OF DATA SHARING FOR BIOMEDICAL RESEARCH?

This briefing paper is produced by the Centre for Biomedicine, Self and Society and draws together key lessons from over ten years of research working with biomedical researchers, data scientists, data controllers, lawyers and ethicists, and extensive public engagement asking: *what makes good governance in data sharing for biomedical research?*

We believe that the public should be data research partners, as outlined in the [consensus statement on public involvement and engagement with data intensive health research](#).

Key issues are:

What does public engagement tell us?

Multiple public engagement exercises have shown that the majority of participants from the general public are largely supportive of uses of personal medical data in health research and this is often described as being in 'the public interest'. However, this support is conditional on a number of factors, for example; what research would be conducted; who would have access to personal medical data and; how this would be controlled.

Take-home message: Good governance of personal medical data is crucial to success and showing trustworthiness in biomedical research. Robust public engagement to inform governance processes is crucial.

What does good governance look like?

The law alone cannot dictate respect for people and their data. It is not enough for researchers to show mere compliance with the law in order to demonstrate good governance and best practice in data sharing. The *care.data* initiative in England was perfectly lawful but it did not secure social licence to make it legitimate and show trustworthiness.

Our research suggests that a principles-based approach to data sharing supports good decision-making and responsible data use. Principles are fundamental starting-points to guide deliberation and action. Principles should be transparent and should reflect the values that underpin any initiative involving data sharing and use. Principles are the common framework of reference for discussion and decision-making around responsible data sharing. Best Practices are examples of principles in action. These are instances of optimal governance in a given context, and suggest which lessons can be learned for data sharing in other contexts.

Take-home message: A good governance framework for data sharing can be grounded in clear principles to guide data practices, and by identifying instances of best practice. For example:

- **Public interest:** Scientifically sound and ethically robust research is in the interest of protecting the health and well-being of the public. Responsible data use to this end should be a stated objective of public bodies holding personal data.
- **Best practice:** It is the data controller's responsibility to ensure the development of *transparent* policies that demonstrate their understanding of public interest and the basis upon which they will use and disclose health data; equally importantly this must include the protection mechanisms under which use will take place.





Further examples of principles and best practices in data sharing can be found here:

[http://www.scot-ship.ac.uk/sites/default/files/Reports/Guiding Principles and Best Practices 221010.pdf](http://www.scot-ship.ac.uk/sites/default/files/Reports/Guiding_Principles_and_Best_Practices_221010.pdf)

What is the public interest and how is this to be decided?

This is a difficult question to answer and always depends on context. Broadly, public interest is linked to demonstrating benefits to the public or parts thereof. Most biomedical research has the potential for public benefit, but often the actual benefit is not traceable or takes many years to materialise. This means that the case for research being in the public interest must always be made; best practice suggests that evidence of public benefit should be gathered and shared widely.

Take-home message: An example of best practice in demonstrating public benefit from data sharing is the #DataSavesLives initiative: https://social.shorthand.com/HeRC_Farr/uywx8Axfif/the-datasaveslives-story

Take-home message: it falls to those who would seek to use personal data for research purposes to make the case that it is in the public interest to access and use data in this way. Public benefits and interests can take a variety of forms, such as direct health benefits, welfare, well-being, improvement to services, efficiencies in uses of public monies etc.

How should public concerns be addressed?

Public engagement exercises show high levels of trust for sharing within the NHS for health-related purposes, but levels of trust are not so high if commercial entities are involved or if data are to be used for purposes that are not directly health-related. This does not mean that non-health uses cannot happen nor that commercial access should not be allowed; rather, it suggests that, rather, that there should be active engagement with stakeholders to identify and address core concerns. For example, security of data and loss of control as data move from one sector to another are often raised as key issues.

Take-home message: Care and effort is needed to identify likely concerns arising from proposed uses of data for research purposes. Active and on-going engagement with stakeholders can both demonstrate trustworthiness and deliver better governance overall.

Key resources:

- **The Scottish Informatics Programme:** <http://www.scot-ship.ac.uk/publications.html>
- **The Farr Institute:** <http://farrinstitute.org/>
- **The Administrative Data Research UK:** <https://www.adruk.org/>

About the Centre for Biomedicine, Self and Society

Our vision is to build an internationally recognised Centre that combines novel, integrative social science and humanities research with innovative approaches to collaboration, stakeholder and public engagement. Our work is anchored in five key research themes. These are: **Beyond Disease**, **Beyond Bodies**, **Beyond Engagement**, **Beyond the Legal** and **Beyond the Global**. We also have a cross-cutting theme **Beyond Data**.



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