



Summary of report

The collection, linking and use of data in biomedical research and health care: ethical issues

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We are generating more data about people's health and biology, from more sources, than ever before including GP records, hospital notes, laboratory tests, clinical trials, monitoring devices and health apps. Advances in information technology and data science mean that it is becoming easier, cheaper and more valuable to gather, transfer, link, store and analyse these data. This offers significant opportunities to generate new knowledge, improve medical practice, increase service efficiency and drive innovation.

The Nuffield Council on Bioethics' report looks at the ethics of data use by considering the relationship between privacy and public interest, and how developments in data science and computing have put significant pressure on conventional approaches to information governance, including the approach of seeking consent or anonymising data for use in research.

More needs to be done to ensure that respect for participants and the protection of their data is at the centre of any initiative, through participation and accountability, backed up by good governance, and criminal penalties for the misuse of data. To marginalise individuals who provide data means risking the trust of current and future generations, exposing people to unacceptable risks, and ultimately missing out on the benefits of research.

The report sets out key ethical principles for the design and governance of data initiatives, and identifies examples of good practice relevant to anyone approaching a data initiative, such as a principal investigator in a research project, lead policy official or commissioner of services.

The report makes a number of recommendations to the UK Government, Department of Health, Independent Information Governance Oversight Panel (IIGOP) and the Health Research Authority (HRA), including:

- Public and private research funders and the Department of Health should ensure there is continued research into the potential harms arising from abuses of data, and should remain vigilant to any new harms that may emerge.
- The IIGOP and HRA should maintain maps of UK health and research data flows, and monitor and evaluate the hazards and potential benefits of new and existing policies, standards, or laws governing the use of health data.
- The UK Government should ensure that privacy breaches involving individual data are reported in a timely and appropriate fashion to the individual(s) affected.
- The UK Government should introduce robust penalties, including imprisonment, for the deliberate misuse of data, whether or not it results in demonstrable harm to individuals.

In relation to the data collected by the NHS, the report makes the following recommendations to the Health and Social Care Information Centre (HSCIC):

- An independent, broadly representative group of participants should be convened to develop a public statement about how data held by the HSCIC should be used.
- There should be complete audit trails of everyone who has been given access to the data, and the purposes to which they have been put. These should be made available to all individuals to whom the data relate or relevant authorities in a timely fashion on request.

Other recommendations are made regarding the governance of data use in research projects.

Copies of the report, short guide and summary are available to download or order from the Council's website www.nuffieldbioethics.org or please contact +44 (0) 20 7681 9619 or bioethics@nuffieldbioethics.org