

Chapter 5

Ethical governance

Chapter 5 – Ethical governance of data initiatives

Chapter overview

This chapter develops an ethical approach to the design and governance of data initiatives and sets out some principles for guidance.

Data initiatives are practical activities that involve a number of actors (who might be individuals, groups, institutions, etc.) some of whom stand to benefit or lose from the outcomes. Tensions and potential conflicts between values and interests can arise at the level of the individual, of professions or of the public. The ethical formation of a data initiative is a matter of reconciling these values and interests in a coherent set of morally reasonable expectations.

A morally reasonable set of expectations should embody four principles:

- the principle of respect for persons
- the principle of respect for established human rights
- the principle of participation of those with morally relevant interests
- the principle of accounting for decisions

The principle of **respect for persons** does not mean that individuals' interests may never be overridden, but that they may only be overridden where there is a legitimate reason to do so. As a principle of design of data initiatives, the principle of respect for **human rights** seeks to avoid potential rights conflicts and violations rather than leaving them to be dealt with retrospectively through judicial processes. The **participation** of people with morally relevant interests allows the identification of relevant privacy norms and the development of governance measures (such as design of consent and authorisation procedures) in relation to these norms; it allows preferences and interests to be expressed and transformed through practical reasoning, and account to be given of how these interests are respected in decision making, helping to foster trust and cooperation. The principle of **accounting for decisions** ensures that expectations, as well as failures of governance and control, are communicated to people affected and to others more widely. It also ensures that data initiatives remain in touch with changing social norms.

Introduction

- 5.1 In chapter 3 we examined the moral values and interests engaged by the collection, retention and use of data in biological research and health care. We saw that private and public interests in these activities are interrelated, often in complex ways, and may be – but are not automatically – in tension. At the end of that chapter we proposed a question to structure reflection on the moral acceptability of data initiatives. They should, we argued, define a set of morally reasonable expectations about how data will be used in the data initiative, giving proper attention to the morally relevant interests at stake. We suggested that an answer should take into account three sorts of considerations: the underlying norms of data access and disclosure, the respect for people in terms of their individual values and interests, and the governance of professional conduct in the public interest. In the previous chapter we examined different legal frameworks and concluded that the minimal conditions they offered did not exhaust or always correspond to morally relevant norms for specific data initiatives. We discussed different consent procedures and concluded that obtaining consent from the 'subjects' of data was not sufficient (or always necessary) to make the use of data

morally acceptable. And we discussed tools and procedures of governance and concluded that they gave only a partial answer to questions of moral accountability.

- 5.2 In this chapter we will take up the question posed at the end of chapter 3 and propose a way of moving, usually in conditions of some uncertainty, from the complex of often poorly articulated and possibly inconsistent values and interests that are engaged by data initiatives to a more coherent, shared and publicly articulated solution. Our approach is based on an understanding of the establishment and conduct of data initiatives as an activity that requires cooperation between people whose interests they engage. We examine how engaging in this activity can inform and develop the relationship between moral norms, individual values and interests, and governance in the public interest, and help to define appropriate governance arrangements. In the course of this we will propose an ethical framework comprising four elements (which are set out in Box 5.1 at the end of the chapter).

Morally relevant interests

- 5.3 Interests are not abstract ideas, existing independently of their bearers and outside time, or unreflective desires demanding satisfaction. They are tied to the people whose interests they are, to a particular material context and orientated towards specific future goals. The contexts in which interests are expressed may involve a number of different people, professions and practices. Indeed, the potential of a data initiative to extract value, and the novel features that give rise to ethical questions, typically result from converging developments in a number of fields of endeavour (for example, the application of computational methods to human biology) rather than a tipping point in the development of any one field. Although no list can be exhaustive, data initiatives in biomedical research and health care might involve:

- Information governance professionals
- Clinicians and other health care practitioners who hold or use data
- Biomedical scientists and researchers (including pathologists, imaging specialists, geneticists, epidemiologists, etc.)
- Social and behavioural scientists
- Bioinformaticians, statisticians and data scientists
- Information technology developers
- Research funders (who may be the public as national taxpayers)
- Commercial firms
- Public policy makers and administrators (service commissioners, etc.)
- Independent advisors (lawyers, bioethicists, etc.)
- Regulators
- Patients or research study participants whose data are included in the initiative (who might also be members of any of the forgoing categories)
- The wider 'public' (or 'publics')²⁵⁸

- 5.4 Along with their skills and resources (including data), each of those involved in a data initiative will bring a particular set of interests and expectations.²⁵⁹ These may be more

²⁵⁸ 'The public' is, of course, a controversial category: see discussion in Nuffield Council on Bioethics (2012) *Emerging Biotechnologies: technology, choice and the public good* (esp. Chapter 5), available at: <http://www.nuffieldbioethics.org/emerging-biotechnologies>.

²⁵⁹ Interests may be in either maintaining or altering these norms, either in the specific case of an initiative or in general.

or less shared and more or less stable within professional or disciplinary groups. (They may be established through professional codes of ethics or good practice guidelines within membership organisations, for example.) But in other cases they may be contested within a given field or profession, perhaps as different ‘schools’ or ‘movements’. They may be further complicated by historical peculiarities, political differences, as well as national traditions and legal contexts (particularly in large international collaborations). The public interest in a data initiative may also be more complex and far-reaching than the immediate aims of the initiative. As well as the immediate aims of the initiative, there may be a public interest in supporting national research or production capacity (so that it can support the development of other products) or even in generating economic activity more generally.²⁶⁰ Two further sets of potentially, but not necessarily, conflicting interests will be those of the public (or of that portion of the public that the data initiative aims to benefit) and those – who may overlap with the first group – from whom the data were collected.²⁶¹

- 5.5 As well as alignments and tensions between professional groups and among individuals within those groups, the interests of individuals themselves can be inconsistent, contrary, and changeable. Research in psychology, behavioural economics, and other social sciences has shown, for example, that the behaviour of individuals in regulating access to and disclosure of private information may not follow rational or predictable patterns.²⁶² One example of this is the so-called ‘privacy paradox’, which refers to the dissonance between individuals’ stated and revealed preferences (for example, people’s stated preferences for privacy and their behaviour using public online social networks).²⁶³
- 5.6 The formation of a data initiative is therefore a complex social practice where tensions and potential conflicts of interests exist at many scales: at the level of the individual, of professions, and of the public. Thinking about data initiatives in this way avoids placing different interests (public and private, researchers and subjects, science and society, etc.) in simple opposition. (See chapter 3 where we drew attention to the mutual implication of public and private interests.) It focuses attention, instead, on how initiatives are formed by those with relevant interests and how, within this context, those involved may collectively develop their moral ‘craft’ through shared

²⁶⁰ A common feature of discourse around innovation is equivocation between the scientific, therapeutic and broader strategic and economic aims (for example, between improving treatments for everyone and beating international competitors in a race to develop those treatments). See chapter 2 (above) for a discussion of this confusion of public interests.

²⁶¹ Health research is generally in the public interest on the basis that any healthy member of the public may be affected by ill health. This is less true for rare hereditary diseases, for example, where the existence of solidarity relations between those at risk and other members of the community comes into the question.

²⁶² Irrational behaviour has a number of explanations including the presence of ‘framing effects’ that distort the appraisal of evidence; preferential modes of reasoning identified by moral psychology that function especially when relevant information exceeds available cognitive capacity; and prevailing social norms. On ‘framing effects’ see Tversky A and Kahneman D (1981) The framing of decisions and the psychology of choice *Science* **211**(4481): 453-8; on ‘moral psychology’ see Haidt J (2012) *The righteous mind: why good people are divided by politics and religion* (New York: Pantheon); on ‘prevailing social norms’ see Utz S and Krämer N (2009) The privacy paradox on social network sites revisited: the role of individual characteristics and group norms *Cyberpsychology: Journal of Psychosocial Research on Cyberspace* **3**(2), article 1, available at: <http://cyberpsychology.eu/view.php?cisloclanku=2009111001&article=1>.

²⁶³ For a survey of evidence about the relationship between what people say and what they do online, see Acquisti A, John LK and Loewenstein G (2013) What is privacy worth? *The Journal of Legal Studies* **42**(2): 249-74, available at: <http://www.heinz.cmu.edu/~acquisti/papers/acquisti-ISR-worth.pdf>. While, for example, the promiscuity of younger generations in online social networking is a popular trope, it is also argued that they are actually more cautious and adept at simultaneously managing multiple interactions governed by different privacy norms. See, for example, Marwick AE and Boyd D (2014) Networked privacy: how teenagers negotiate context in social media *New Media and Society* **17**(6): 1051-67.

understanding of ‘good practice’.²⁶⁴ It also suggests that the elucidation of relevant interests should be an important initial step in the formation of a data initiative.

Morally reasonable expectations

- 5.7 The interests that apply to different data initiatives will vary according to the initiative in question. Nevertheless, there is a general need to find a way of reaching decisions about the use of data that command respect, particularly among those who may feel that their own preferences have not prevailed. If the decision-making process lacks moral legitimacy, they may feel that their interests have been disregarded by others, especially to the advantage of those with greater political, economic or social power.

Moral reasonableness

- 5.8 The question with which we concluded chapter 3 concerned what it might be reasonable for those who participate in data initiatives to expect concerning the use and control of the data. There are broadly two ways in which something might be argued to be ‘morally reasonable’. First, a proposition might be morally reasonable if it conforms to an objective moral standard or principle. What establishes that standard and who judges conformity with it are therefore important second-order questions. Second, a proposition might be judged to be reasonable where it is the outcome of a legitimate procedure, for instance democratic decision making.²⁶⁵ In this case, who participates in this procedure and how it is conducted are equally important secondary questions.
- 5.9 The weakness of approaches based on substantive principles is that if they are too abstract they leave open a wide margin of interpretation concerning how they should be applied. If they are too prescriptive they may proscribe solutions that can optimise ethical data use according to legitimate and possibly diverse values. Purely procedural approaches, on the other hand, can result in morally perverse outcomes if they are not constrained or guided by some principle (as we noted in chapter 3). Procedural approaches therefore generally include an appeal to objective moral standards that both legitimise and place some limitations upon the relevant procedures. The approach we propose here has a strong procedural dimension – emphasising both participation and accountability – but is grounded in and constrained by a strong commitment to ‘respect for persons’.

Principle 1 – Respect for persons

The set of expectations about how data will be used in a data initiative should be grounded in the principle of respect for persons. This includes recognition of a person’s profound moral interest in controlling others’ access to and disclosure of information relating to them held in circumstances they regard as confidential.

²⁶⁴ See Parker M (2012) *Ethical problems and genetics practice* (esp. chapter on ‘moral craft’ pp. 112-30) Cambridge: Cambridge University Press).

²⁶⁵ An example of this approach is outlined by Normal Daniels under the rubric ‘accounting for reasonableness’: see Daniels N (2000) Accountability for reasonableness: establishing a fair process for priority setting is easier than agreeing on principles *British Medical Journal* **321(7272)**: 1300-01, available at: http://www.bmj.com/content/321/7272/1300?ijkey=e1c0e7705033bda924d2556bec2d6af8da87175d&keytype=tf_ipsecsha.

- 5.10 The principle of respect for persons is the principle that all persons have a special moral status that means they are owed respect simply in virtue of being persons and not because of any contingent characteristics, individual merit or social position.²⁶⁶ Respecting persons takes the practical form of treating persons in ways that have regard to their own interests, not merely treating them as tools to secure our own ends or gratification.²⁶⁷
- 5.11 The principle of respect for persons, with regard to information access and disclosure, implies that consideration should be given to how their wishes about certain uses of information should be taken into account. This does not imply simply doing what people want. In many cases the things that different people want are incompatible. Data initiatives are collective activities that require cooperation. What is 'reasonable' in the context of a data initiative must, therefore, pay appropriate respect to all those with morally relevant interests. It means, furthermore, that the initiative should not assume that their interests can be respected simply by taking account only of the interests of a family, tribe, community, or nation to which they belong.
- 5.12 There may be rare cases in which a data initiative may depend on people accepting something (the disclosure of certain data relating to them, for example) that they would prefer not to happen. This is not always incompatible with respect for persons, even in the face of their active and specific objections. There are two main cases in which the argument for mandatory inclusion of individual data in a dataset by appeal to necessary and proportionate interference is made (see paragraph 4.5). The first case is where an aim of paramount public interest can only be achieved by either comprehensive participation (or could not be achieved by a level of participation expected under non-compulsory conditions) or can only be achieved by the inclusion of particular individuals. Such cases as these arise (although not without controversy) in the domain of public health, where individual objections to state intrusion into private life are sometimes overruled in the public interest. Limitations of this sort underpinned a series of Vaccination Acts in the UK in the 19th Century (for the eradication of smallpox) and may be invoked in contemporary public health emergencies.²⁶⁸ A relatively uncontroversial example is the mandatory reporting by doctors of 'notifiable' diseases.²⁶⁹ The second case is one in which full participation is not necessary, but where it can be argued that 'free riding' (*i.e.* benefitting from a public good that others have borne the cost of providing) is regarded as morally unacceptable. Some have sought to apply this argument to national health data initiatives to develop or improve medical treatments or care.²⁷⁰

²⁶⁶ Philosophers have argued about the criteria for being a 'person' and whether it applies to 'marginal cases' (e.g. neonates, people with severe cognitive impairments, or cognitively advanced higher primates or computers). Such considerations may become operationally relevant when decisions about data relating to particular subjects fall to be made.

²⁶⁷ Philosophical support for the principle is usually derived from the work of the Prussian Enlightenment philosopher, Immanuel Kant. See: Kant I (1785 [1785]) *Groundwork of the metaphysics of morals* (Cambridge: Cambridge University Press).

²⁶⁸ The 1853 Act, for example mandated vaccination of every infant whose state of health would stand it and registration of the fact with the registrar of births. See: Porter D and Porter R (1988) The politics of prevention: Anti-vaccination and public health in 19th century England *Medical History* 32: 231-52, available at: <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1139881/pdf/medhist00062-0007.pdf>.

²⁶⁹ A duty is placed on a doctor to notify the relevant local authority officer if they suspect that a patient has a 'notifiable disease' under the Public Health (Control of Disease) Act 1984 (<http://www.legislation.gov.uk/ukpga/1984/22>) and Public Health (Infectious Diseases) Regulations 1988 (<http://www.legislation.gov.uk/uksi/1988/1546/contents/made>). For the legal basis of information sharing in relation to health, see: Department of Health (2007) *NHS information governance. Guidance on legal and professional obligations*, available at: <http://systems.hscic.gov.uk/infogov/codes/lglobligat.pdf>.

²⁷⁰ See: Chan, Sarah and Harris, John. 2009. Free riders and pious sons – why science research remains obligatory *Bioethics* 23(2): 161-171, available at: <http://onlinelibrary.wiley.com/doi/10.1111/j.1467-8519.2008.00648.x/full>; Stjernschantz Forsberg

- 5.13 The fact that some data initiatives involve relationships between individuals and the state, which, as is often said, has a monopoly on the legitimate use of force to require compliance where it is not freely given, gives rise to our second requirement, concerning human rights.

Principle 2 – human rights

The set of expectations about how data will be used in a data initiative should be determined with regard to established human rights. This will include limitations on the power of states and others to interfere with the privacy of individual citizens in the public interest (including to protect the interests of others).

- 5.14 Some data initiatives have been challenged in the courts because they have been seen as breaching privacy rights enshrined in UK and European law.²⁷¹ The mechanics of the judicial process, however, mean that the acceptability of a practice may not be tested until there is a victim. It is often the case that the evolution of the law lags behind the invention of new initiatives and in some cases behind the evolution of social norms (although in some cases it can encourage such evolutions, as with the recognition of the rights of certain minorities). For reasons that we discussed in chapter 2, in the case of data abuses there can be a long interval between the cause of the harm and the effect, and abuses may continue for years before a harm is detected and addressed. Furthermore, as our commissioned research showed, it is necessary to consider a broader range of morally relevant effects than might meet the standards of harm required to engage legal rights.²⁷² A final consideration against merely relying on the judicial process is that seeking relief might actually compound the harm by drawing attention to it, so ‘victims’ may be unwilling to take action.
- 5.15 The purpose of promoting human rights as a formative principle for data initiatives is therefore to encourage a prospective consideration of how conflicts might arise and how they might be resolved (particularly where legal provisions are inadequate, inaccessible, unclear or conflicting), or avoided altogether. The aim is also to encourage the foundation of data initiatives on the moral rights that underpin legal systems, rather than to focus on simply satisfying the requirements of positive law, possibly on the construction most favourable to the aims of the initiative (and not necessarily to the interests of all those affected by it).
- 5.16 The principle of respect for persons and the requirement to respect human rights set the criteria for what expectations about the use of data may qualify as morally reasonable. Together, they provide the substantive ‘guide rails’ for the formation of morally acceptable data initiatives, without prescribing what specific measures should be adopted in the context of any particular data initiative. Within these bounds we still need to determine how the relationship between the relevant norms, the interests of

J, Hansson MG, and Eriksson S (2014) Why participating in (certain) scientific research is a moral duty *Journal of Medical Ethics* 40: 325-8, available at: <http://jme.bmj.com/content/40/5/325.short>.

²⁷¹ An example of an initiative subject to a successful claim is the UK National DNA Database (see *S. and Marper v. The United Kingdom*; <http://www.bailii.org/eu/cases/ECHR/2008/1581.html>).

²⁷² See: Laurie G, Jones KH, Stevens L, and Dobbs C (2014) *A review of evidence relating to harms resulting from uses of health and biomedical data*, available at: www.nuffieldbioethics.org/project/biological-health-data/evidence-gathering/.

individuals and the external controls of governance should be resolved in any given concrete situation.

Moral reasoning

- 5.17 While individual interests may sometimes be overridden in the public interest, more usually, however, people will accept outcomes that they would not necessarily prefer because they are an indissociable part of a 'bundle' of goods that they value. This may be the case, for example, with freely provided Internet services, where users 'trade off' some unfavourable 'terms and conditions' in order to gain access to a service.²⁷³ This, however, assumes that people are mere consumers, reduced to accepting or refusing an option presented to them, or choosing between several available 'offerings'. Where the question is about the design of a data initiative rather than selection from among a number of available options, it is no longer a matter of evaluating the different tradeoffs as a consumer but instead about negotiating between the moral interests of different participants (where one 'participant' may represent the 'public interest'). There are strong reasons to believe that, in the case of data initiatives in which questions of public interest are at stake, involving those with interests in the design and conduct of the initiative is preferable to simply offering pre-determined options, not least because there is a public interest in the optimisation of outcomes for all. Rather than treating norms and values as fixed or imponderable, such an approach may offer a way of bringing these into play in order to produce a new equilibrium within a particular governed context.
- 5.18 One way in which decision makers have sought to understand prevailing norms in society is through research into public opinion. A number of qualitative and quantitative exercises, including surveys, consultations and public dialogue events, have been carried out into the use of data for biomedical research and other purposes. These have mainly been sponsored by research funders, who typically want to understand how use may legitimately be made of available data resources and to promote public trust in research. A body of received wisdom that claims support from these findings has built up in the UK about the use of stored information. This suggests that there is a broad majority of public support for information to be used for a range of secondary purposes (including in biomedical research and health service improvement) *so long as* people are asked about this. However, this support is said to fall away to a significant extent where they are not asked, or where the research involves private companies operating for profit.²⁷⁴ The current reality of medical research is that it relies upon

²⁷³ There is a well-known apothegm in information technology that if someone is not paying for the service, 'they're not the consumer, they're the product', meaning that the reason they are able to obtain the service without payment is that the service provider is able to make a return by selling data provided (when registering for or using the service) or somehow monetise it thereafter. See: <http://blogs.law.harvard.edu/futureoftheinternet/2012/03/21/meme-patrol-when-something-online-is-free-youre-not-the-customer-youre-the-product/>.

²⁷⁴ The published evidence comes from a mixture of commissioned market research and academic social science. See Hill EM, Turner EL, Martin RM, and Donovan JL (2013) "Let's get the best quality research we can": public awareness and acceptance of consent to use existing data in health research: a systematic review and qualitative study *BMC Medical Research Methodology* **13**(1): 72, available at: <http://www.biomedcentral.com/1471-2288/13/72>. The Consultation response by Ian Herbert (available at: www.nuffieldbioethics.org/project/biological-health-data/evidence-gathering/) also provides a very helpful list of relevant research, drawn from his 2012 report *Fair shares for all: sharing and protecting electronic patient healthcare data*, available at: <http://phcsg.org/publications/fair-shares-for-all-final/>. Subsequent relevant research includes Ipsos MORI *Dialogue on data: exploring the public's views on using administrative data for research purposes*, available at: http://www.esrc.ac.uk/_images/Dialogue_on_Data_report_tcm8-30270.pdf; CM Insight research for Wellcome Trust (2013) *Summary report of qualitative research into public attitudes to personal data and linking personal data*, available at: <http://www.wellcome.ac.uk/About-us/Publications/Reports/Public-engagement/WTP053206.htm>; Sciencewise ERC (2014) *Big data: public views on the collection, sharing and use of personal data by government and companies*, available at: http://www.sciencewiseerc.org.uk/cms/assets/Uploads/SocialIntelligenceBigData.pdf?utm_medium=email&utm_source=Ricardo-AEA+Ltd&utm_campaign=4132283_SWpercent2fMonthly_digestpercent2fNAOpercent2fED57482500_May+2014&dm_i=DA4,2GKHN,1SUKGU,8Y5R6,1; Ipsos MORI's research on trust in data and

clinical and commercial research collaborations and partnerships to develop innovations for the health care system (see chapter 2 above). Difficult issues therefore arise, for example, if data are collected initially through the health care system or academic institutions and then access is given to a pharmaceutical company as a part of collaborations.²⁷⁵ It is not clear, however, that these details are considered when people give their opinions to researchers.²⁷⁶ This evolving area would benefit from further research. As some of the academic papers acknowledge, the research may suffer from a sample bias that favours participants who are positive about research.²⁷⁷

- 5.19 While public opinion research gives a valuable indication of some relevant norms its limitations as a support for decision making must be understood. It presents decision makers with a number of difficulties, not least the value that should be given to opinions from the interested and the disinterested, those informed by morally relevant interests or those informed by merely prudential or even immoral ones, those that are top-of-the-head and those that result from earnest and prolonged deliberation.²⁷⁸
- 5.20 Public opinion research typically provides evidence in decision making where the actual decisions are taken elsewhere, in contexts to which access is restricted and through procedures that are often obscure.²⁷⁹ In the case of data initiatives there are reasons to give particular attention to people whose morally relevant interests are engaged, not simply as a source of evidence of the norms that must be managed, but as collaborators in the elaboration of the whole system. This means not only the professionals who deliver it and those who stand to benefit but also – and perhaps most importantly – people whose privacy and welfare are at stake. This can be prudent because their decisions about whether to participate or not can enable or frustrate the initiative once it is established. But it also expresses respect for them as persons who have morally significant interests and the capacity to contribute positively to the shaping of the social world.
- 5.21 In chapter 3 we discussed a number of ways of resolving problems of collective action. We mentioned common good, social contract and utilitarian approaches to these problems and noted that all had advantages and disadvantages.²⁸⁰ If individuals are to be included there are two main ways in which their interests may be brought to bear

attitudes toward data use/data sharing for the Royal Statistical Society (2014), available at:

<http://www.statslife.org.uk/news/1672-new-rss-research-finds-data-trust-deficit-with-lessons-for-policymakers>.

²⁷⁵ See: Ipsos MORI for MRC (2007) *The use of personal health information in medical research*, available at: <http://www.mrc.ac.uk/documents/pdf/the-use-of-personal-health-information-in-medical-research-june-2007>, which found pharmaceutical companies to be among the least trusted organisations where personal health information is concerned (trusted by just 6 per cent of the population, confirming long-standing trends research on general trust in professions).

²⁷⁶ Clemence M, Gilby N, Shah J, et al. (2013) *Wellcome Trust monitor wave 2: tracking public views on science, research and science education*, available at: http://www.wellcome.ac.uk/stellent/groups/corporatesite/@msh_grants/documents/web_document/wtp053113.pdf.

²⁷⁷ For such an acknowledgement, see Hill E, Turner E, Martin R and Donovan J (2013) "Let's get the best quality research we can": public awareness and acceptance of consent to use existing data in health research: a systematic review and qualitative study *BMC Medical Research Methodology* 13(1): 72, available at <http://www.biomedcentral.com/1471-2288/13/72>.

²⁷⁸ On the problems and paradoxes of public engagement, see Nuffield Council on Bioethics (2012) *Emerging biotechnologies: technology, choice and the public good*, especially chapter 5 ('Public perspectives'), available at: <http://www.nuffieldbioethics.org/emerging-biotechnologies>.

²⁷⁹ This is self-consciously true of government which reserves a 'safe and protected space' for policy making. See also: Nuffield Council on Bioethics Nuff' said blog (4 February 2013) *Engagement in open policy making; or how to train your academic*, available at: <http://nuffieldbioethics.org/blog/2013/engagement-in-open-policy-making-or-how-to/>.

²⁸⁰ See paragraph 3.19ff.

fairly, namely through aggregation or deliberation.²⁸¹ The basic difference is that aggregative approaches assume that people have stable or rational preferences from which the preferences of the group can be deduced, whereas deliberative approaches place value on the fact that individual moral interests in collective outcomes may be transformed as they encounter each other in a context of reasoned argument and discussion.²⁸²

- 5.22 A deliberative approach may address the complex problem of resolving varied, confused, and possibly conflicting norms and interests into a coherent and mutually acceptable set of common aims and expectations.²⁸³ This demonstrates respect for persons because (and insofar as) it arises from the face-to-face encounter between moral agents who recognise and treat each other as such.²⁸⁴ It also recognises that the elements of any solution (the norms, mechanisms to account for diverse values and forms of governance) are interrelated and co-dependent.

Principle 3 – Participation

The set of expectations about how data will be used (or re-used) in a data initiative, and the appropriate measures and procedures for ensuring that those expectations are met, should be determined with the participation of people with morally relevant interests. This participation should involve giving and receiving public accounts of the reasons for establishing, conducting and participating in the initiative in a form that is accepted as reasonable by all. Where it is not feasible to engage all those with relevant interests – which will often be the case in practice – the full range of relevant values and interests should nevertheless be fairly represented.

- 5.23 The principle of participation requires decision makers not merely to imagine how people with morally relevant interests *ought* to expect data to be used but to take steps to discover how they do, *in fact*, expect data to be used and to engage with those expectations. The participation of people with interests at stake in the design of data initiatives gives decisions a strong claim to legitimacy. Independently of the outcome, participants, and the wider public, are more likely to accept the process as being a fair and respectful way of resolving any differences between them with regard to decisions that may affect them all.²⁸⁵
- 5.24 The outcome of such a process is by its nature provisional, a ‘working solution’. Circumstances or expectations may change; they may prove unrealistic; there may be

²⁸¹ Both aggregation and deliberation have a claim to procedural fairness. See also: Knight J and Johnson J (1994) Aggregation and deliberation: on the possibility of democratic legitimacy *Political Theory* **22(2)**: 277-96; Gutmann, A and Thompson D (2004) *Why deliberative democracy?* (Princeton: Princeton University Press).

²⁸² Daniels and Sabin note that moral values are not simply like tastes or preferences: aggregation “seems insensitive to how we would ideally like to evolve moral disputes, namely through argument and deliberation.” Daniels N and Sabin J (1997) Limits to health care: fair procedures, democratic deliberation and the legitimacy problem for insurers *Philosophy and Public Affairs* **26(4)**: 303-50, at page 338.

²⁸³ There are a number of well-known advantages and disadvantages of deliberative approaches. Some of these are discussed in Parker M (2007) Deliberative bioethics, in Ashcroft RE, Dawson A, Draper H, and McMillan JR (Editors) *Principles of health care ethics* (Chichester: John Wiley & Sons), pp185-91.

²⁸⁴ Among the implications of the principle of respect for persons is not only a respect for the things that persons value but also a recognition that they themselves can, when they are enabled to do so, take responsibility with others for actively creating the conditions that, for example, manage their privacy and promote the common interest. Furthermore, it is an implication of respect for persons that this is morally preferable (*i.e.* more respectful) when this is done by those people themselves or through their nominated representatives.

²⁸⁵ See also guidance outlined in the recent report for Sciencewise, *Data policy and the public: shaping a deeper conversation*, available at: <http://www.sciencewise-erc.org.uk/cms/assets/Uploads/Data-policy-and-the-publicJan-2015.pdf>.

improvements or failures. Consequently, though the process may be provisionally concluded with the production of a publicly storable set of expectations about how data will be used and governed, there is often a need for continuing reflection and review. The principle of participation therefore applies equally to the establishment of a data initiative and to its continuing governance.

Accounting for decisions

- 5.25 Deliberation is a social activity that requires participants to engage in a common ‘public’ discourse through which they can account to each other for the positions they take.²⁸⁶ This accounting, given through a face-to-face encounter between moral agents with a common purpose, can build trust among people with different interests, allow them to discover where trust may be placed intelligently and design the terms of a data initiative accordingly.²⁸⁷ Like any social activity, however, deliberation is vulnerable to abuse, domination or capture by those with power.²⁸⁸ It is also at risk from cognitive and social effects such as framing and ‘groupthink’.²⁸⁹ There are two main antidotes to these effects: the internal commitment to fair conduct, and openness to external scrutiny and revision. It is important, therefore, that the initiative is embedded in broader system of accountability that allows for challenge and dispute resolution. The notion of accountability emphasises the extension of the processes of moral deliberation, namely the requirement to ‘give an account’ that is intelligible and acceptable to the person to whom it is given. It also emphasises the function of ‘holding to account’, namely the imposition of a judicial power with legitimate authority.

Principle 4 – Accounting for decisions

A data initiative should be subject to effective systems of governance and accountability that are themselves morally justified. This should include both structures of accountability that invoke legitimate judicial and political authority, and social accountability arising from engagement of people in a society. Maintaining effective accountability must include effective measures for communicating expectations and failures of governance, execution and control to people affected and to the society more widely.

- 5.26 The principle of ‘accounting for decisions’ emphasises two forms of accountability that face in notionally divergent directions. The first is formal accountability, through regulatory, judicial and political procedures. In a democratic society this should be

²⁸⁶ This notion of the public use of reason that claims the right of reason to challenge authority draws on a modern tradition from Kant (*What is enlightenment?*) that has found different contemporary expressions in European thinkers such as Jürgen Habermas (*Moral consciousness and communicative action*) and proponents of deliberative democracy (e.g. Amy Gutmann; Norman Daniels).

²⁸⁷ For a discussion of the significance of trustworthiness and the placing of trust, see: O’Neill O (2002) *Autonomy and trust in bioethics* (Gifford Lectures 2001) (Cambridge: Cambridge University Press). It seems preferable to construct an initiative in conditions that foster trust, and that allow the interrogation of and making provision for the limits of trustworthiness, rather than simply to treat participants as consumers in a free market of more or less trustworthy initiatives.

²⁸⁸ Those able to exploit differentials of knowledge, articulacy, economic and political power, for example.

²⁸⁹ On framing see Tversky A and Kahneman D (1981) The framing of decisions and the psychology of choice *Science* **211(4481)**: 453-8; on ‘groupthink’ see Turner ME and Pratkanis AR (1998) Twenty-five years of groupthink theory and research: lessons from the evaluation of a theory *Organizational Behaviour and Human Decision Processes* **73(2/3)**: 105-15, available at: http://homepages.se.edu/cvonbergen/files/2013/01/Twenty-Five-Years-of-Groupthink-Theory-and-Research_Lessons-from-the-Evaluation-of-a-Theory.pdf.

accessible to those with a relevant moral interest (potentially up to the level of the whole political community where the data initiative in question raises issues of public policy). The second is accountability to the broader mass of moral stakeholders who, perhaps for practical reasons, cannot participate directly in the formation or governance of the initiative. Periodic engagement with a broader public, for example, provides a way of ensuring that they are fairly represented and that governance is not ‘captured’ by partial interests. Formal and social accountability are closely linked, as a system that loses its social mandate will come under pressure politically. However for either to work, people (and in particular the dispersed and potentially vulnerable participants whose information is used) need effective means of learning what has happened to their data. This inevitably requires a careful consideration of the design not just of the systems that a given data initiative calls into being, but of the institutional structures in which they are embedded, to ensure that there is sufficient transparency and incentives to report abuses and to rectify them.²⁹⁰

Conclusion

- 5.27 The question we posed at the end of chapter 3 was: ‘How may we define a set of morally reasonable expectations about how data will be used in a data initiative, giving proper attention to the morally relevant interests at stake?’ Different data initiatives will have different objects, engage different moral values and interests, and give rise to different sets of expectations. We have suggested that a good answer may be given through a procedure of moral reasoning that is bounded by respect for persons and human rights, involves the participation of those representing the range of morally relevant interests at stake, and is embedded in institutional and social procedures for accountability.
- 5.28 With these principles in mind, in the following chapters we consider a number of concrete data initiatives in order to highlight instances of good practice and areas where attending to these principles may offer better solutions than those that have been found.

Box 5.1: Summary – ethical principles for data initiatives

The use of data in biomedical research and health care should be in accordance with a publicly statable set of morally reasonable expectations and subject to appropriate governance.

- **The set of expectations about how data will be used in a data initiative should be grounded in the principle of respect for persons.** This includes recognition of a person’s profound moral interest in controlling others’ access to and disclosure of information relating to them held in circumstances they regard as confidential.
- **The set of expectations about how data will be used in a data initiative should be determined with regard to established human rights.** This will include limitations on the power of states and others to interfere with the privacy of individual citizens in the public interest (including to protect the interests of others).
- **The set of expectations about how data will be used (or re-used) in a data initiative, and the appropriate measures and procedures for ensuring that those expectations are met, should be determined with the participation of people with**

²⁹⁰ See recommendation 3.

morally relevant interests. This participation should involve giving and receiving public account of the reasons for establishing, conducting and participating in the initiative in a form that is accepted as reasonable by all. Where it is not feasible to engage all those with relevant interests – which will often be the case in practice – the full range of values and interests should nevertheless be fairly represented.

- **A data initiative should be subject to effective systems of governance and accountability that are themselves morally justified.** This should include both structures of accountability that invoke legitimate judicial and political authority, and social accountability arising from engagement of people in a society. Maintaining effective accountability must include effective measures for communicating expectations and failures of governance, execution and control to people affected and to the society more widely.