Global Alliance for Genomics and Health: Consent Policy
Version: 24 April 2015-05-20

The Nuffield Council on Bioethics is an independent body that examines and reports on the ethical issues in biology and medicine. We have recently published the report *The collection, linking and use of data in biomedical research and health care: ethical issues* (the 'Nuffield Report'), which is relevant to the proposed consent policy and on which we draw in the feedback provided below.

Objective and Context

- *" The objective of this policy is to guide the sharing of genomic and health-related data ('Data') in a way that respects autonomous decision-making while promoting the common good of international data sharing"*[1]

International, collaborative research initiatives need to accommodate differing local practices and tackle complex consent issues to do with re-use and international transfer of data. The use of cloud-based storage and processing services is becoming increasingly important but it also raises issues such as third party access (Nuffield Report, chapter 7, p.128).

It might be useful to clarify the notion of "common good" here. Extended international data-sharing is not self-evidently a "common good" and can put in question data protection concepts and underlying ethical values.

The Nuffield Report discusses this question in relation to 'public interest' and "objectives that are valued by society" in the context of collective decision making (chapter 3, 3.18ff).

Regarding respect for autonomous decision-making, more detail might be provided about how this concept is related to the concept of respect for human rights in data initiatives. Are other values or principles included in the policy, or is the account of autonomy limited to the decision to share data at the outset of a project? In the Nuffield Report, four ethical principles are set out (chapter 5, p. 84).

[1] p.1 (Preamble).

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

We argue that designing a data initiative in conformity with these principles should help data initiatives not only to meet standards of moral acceptability but also to promote the public interest. We argue, furthermore, that consent alone is neither necessary nor sufficient to protect the significant moral interests of those whose data are involved in a data initiative, and that explicit consent is, furthermore, only one mode of expression of moral agency, the appropriate form of which should be determined in consideration of two other, equally significant considerations. These are (1) the underlying moral norms of privacy and disclosure on which a proposed use of data may trespass, and (2) the form of governance of professional conduct. We believe that insufficient attention to the relationship between these three factors (social norms, respect for the moral subject and the moral duties of professionals) can lead – and in some cases has led – to suboptimal, counterproductive or self-defeating outcomes.

- *"The Framework applies to use of data that have been consented to by data donors (or their legal representatives) and/or approved for use by competent bodies or institutions in compliance with national and international laws, general ethical principles, and best practices that respect restrictions on downstream uses"*[2]

- *[...] "It can help to determine if data sharing is indeed covered in the existing consent or if re-contact with notification and opt out or, re-consent or other forms of approvals or social engagement are necessary to enable data sharing. It can also help to ensure that genomic and health-related data within the GA4GH ecosystem are harmonized across organizations, bodies and countries to the greatest extent possible. "*[3]

Recommendation 17 of the Nuffield Report states:

> The research community, including all academic and commercial partners, data controllers and custodians, public services and government agencies should actively foster opportunities to create a more explicit and reflective foundation for extending data access in the public interest. We urge all stakeholders in the medical research

[2] p.1 (Context).
[3] P. 1-2 (Context).

enterprise to continue to develop robust and comprehensive, yet efficient privacy protecting rules, guidelines and measures. Among other things these should aim at:

> ■ Providing greater clarity for members of the public about
> ways that their biomedical data are used, and may be used in the future, along with a realistic acknowledgement that no system can guarantee privacy and confidentiality in all circumstances.
>
> ■ Securing commitments from data controllers to a responsible approach to the extension of data access as part of their core mission statement; they must publish information about their approach to data access, transparency and accountability,
> and whether, and on what terms, they will consider extending access to data.
>
> ■ Demonstrable and continual improvement of collection, storage and data access procedures against explicit standards for accuracy, reliability and security (exec. summary, p. 26; cf. chapter 8, p. 156).

We also recommend that professionals involved in data initiatives involve a range of those with morally relevant interests in the design of the data initiative in order to arrive at a publicly statable set of expectations about how data will be used (chapter 5, p. 94). Involving a range of participants in the design and governance of a data initiative so that their interests and values can be expressed, transformed and reconciled, allows initiatives to be optimised for the public interest, beyond the requirements of the law. See also:

> **Principle 3**
>
> 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. (chapter 5, p. 92).

Consent Best Practices

- *"Consent is one of the bedrock principles underlying the ethical conduct of clinical practice and research involving humans. The practice of seeking and receiving informed consent from data donors shows respect for their ability to make their own decisions, as well as respect for the practices of medicine and research."* [4]

Consent, as outlined in the Nuffield Report, is not so much a 'balancing tool' (as seems suggested by the above quote), and we caution against an over-emphasis or over-reliance on consent with respect to its moral functions.

> 3.12 [...] while observing the terms of consent respects the interests of the person giving it in a limited way, the fact that information is only disclosed in accordance with the terms of the consent does not in itself protect the person from any harm resulting from the use of the information.
> Thus, consent should not be thought of as shifting the liability for any privacy infringements from the user of data to the 'consenting' person, and simply obtaining consent does not exhaust the moral 'duty of care' owed by the user of the data. [...] Consent is often, in fact, a rather blunt tool, allowing only a binary 'yes' or 'no' response. Genuine respect for the autonomy of individuals as 'world forming' is likely to be better realised through a richer involvement in the formation of norms and options than simply accepting or refusing options presented by others.

3.13 Consent is neither always necessary (since not all norms would otherwise prohibit data access and disclosure) nor sufficient (since it does not set aside the moral duty of the user of data with respect to others) for ethical use of data. However, where there is a reasonable expectation that disclosure of information may infringe a well-grounded entitlement to privacy, consent may play an important role in enabling that disclosure (chapter 3, p. 51-52).

Privacy, Data Protection and Confidentiality

- *"Consent materials should specify how confidential data will be protected, such as through coding or anonymization, in accordance with applicable laws and/or guidelines."* [5]

The Nuffield Report emphasises the difference between norms and values related to confidentiality and privacy, and technical procedures of anonymisation and coding. It

[4] p.3.
[5] p. 4 (Accountability).

is therefore important to distinguish between these concepts – the application of particular technical procedures to data does not discharge users of data of moral responsibility associated with confidentiality and privacy, although these are not absolute and are also context-dependent (chapter 3, p. 46ff.; 4, p. 62).

Risk-Benefit-Analysis

- "Special attention should be placed on the protections afforded to vulnerable persons or populations in the seeking and obtaining of consent, to prevent exploitation and facilitate proper representation without unnecessarily excluding them from research."[6]

We welcome the inclusion of this reference to vulnerable persons or populations. More specifically, we recommend that the formation of any data initiative takes special care to identify those interests that may be especially at risk or that arise from diverse values. Identifying situational vulnerabilities (i.e. why the consequences of a particular data initiative might disproportionately affect certain individuals or groups) and understanding how different people value the potential benefits and hazards of data initiatives is essential to explore what forms of respect for individual freedoms (e.g. consent) and forms of governance may be required (chapter 8, p. 157).[7]

[6] p.5 (Risk-Benefit-Analysis).
[7] The context-dependence of vulnerability is also discussed in detail in the new Nuffield Council report "Children and clinical research: ethical issues".