

This response was submitted to the consultation held by the Nuffield Council on Bioethics on *The linking and use of biological and health data* between 17 October 2013 and 10 January 2014. The views expressed are solely those of the respondent(s) and not those of the Council.

Response:

The following notes refer to Consultation question 1. (**Do biomedical data have special significance?**) & 2. (**What are the new privacy issues?**). Some of these are based on /linked to ideas in the academic bioethical debate that I did not make explicit. Please get back to me should you have any questions.

- “Biomedical data”: Potentially extremely large class of data merging in particular *personal and research data*
- A distinct *phenomenon*, though seemingly *not a distinct class* of data in a legally operative way
- Biomedical data, are, perhaps, not exceptional, but still *peculiar*, in analogy to the debate concerning *genetic information* – this is because of the characteristics of genetic data insofar these are implied here (stable, predictive information from extremely small sources with supra-individualistic relevance) *plus* the features of big data type research and emerging research infrastructures the organization and pursuit of which runs counter traditional ideas of “confidentiality” and “privacy” (even given divergence in the interpretation and concrete values underpinning these concepts), see in particular intentional accumulation, linking and sharing for future unanticipated, global use - being contra the idea of *data minimization*
- This would mean that *both qualitatively and quantitatively*, biomedical (big) data comprise *new-level phenomena* which require *regulatory* response
- As for the *legal status* of this large class of data, relevant *subclasses* should be differentiated with an eye on ethical and policy aims as well as legal operability
- As concerns *ethical* issues and sensitivity tied to these phenomenon, in particular the merging – in ethical and regulatory response – of data issues that have traditionally been protected by individual-level human rights and research data seems problematic
- This problem in turn has at least 2 main sub-problems: the potential relevance of genetic/genomic/epigenetic data for persons beyond the individual source and the already incipient move towards “*open data*” as concerns research data
- These broad sets of data are not always comprising sensitive information, but the aims in the traditional concepts underpinning their protection and status radically diverge: privacy has been conceived of as an individual level right; it seems premature, on the other hand, to govern towards a general culture of open data *comprising* biomedical data before the issue of a potential right to know/ not to know concerning e.g. medically relevant information and the *prima facie* altogether different issue of extensive research data sharing (and the implications for the various forms of intellectual property protection in the life sciences) is more adequately publicized and addressed

- In short: *open data does not imply open consent* in any coherent argument, at least as long as there is adherence to individual-level human rights in biomedicine (e.g. Oviedo Convention), i.e. even though biomedical data are presumably not intrinsically more sensitive than other classes of data, the human rights tradition recognizes a primacy and at least *prima facie sovereignty over the personal individual sphere* (which is not “ownership”, but seems to have a certain overlap with in particular the values informed consent protects and the rights it confers)
- On the other hand, even within this tradition, if there is, e.g., a strong ‘right to participate in the advancement of science’, there might be correlative duties to share biomedical data. Yet, it seems that the moral primacy of individual rights (and therefore, minority rights e.g.) should not be easily given up. In more practical, governance-oriented terms, however, it seems that a potential clash should be resolved within a given context (e.g direct-to-consumer genetic services). For larger long-term policy response, it seems that this would imply that duties to share biomedical must be coupled to much clearer definitions and policy proposals of intended public benefits, as for healthcare, science etc. that might ground new forms of “solidarity”.

A general comment:

The language used in the consultation report refers to “ethical” linking, “ethical” use of data, “ethical” research activities. From a philosophical point of view, this is vague if not meaningless, and I think does not help to inform the public (debate), because it gives the impression that the (only) right kind of treatment of data/ research practice can be inferred (perhaps only) from observing social/ cultural practice. “Ethical” instead refers solely to different philosophical schools (utilitarian, Kantian, ...) underpinning particular ethical arguments. There is no such thing as an “ethical use”, but only uses that comply with particular conceptions of the good. While, for example, it might be true that some persons’ views about some kind of “privacy” is changing given their behaviour in social media, nothing obvious follows from this as for what is the morally right thing to do concerning data protection in general or biomedical data protection more specifically.