

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.

I have looked at the consultation document and include here **some general comments that relate somewhat to Consultation Questions 1, 2 and 4 most closely.**

When considering biomedical data as a distinct class of data, it may be useful to examine the ethical issues raised in a very useful report that looks at data in the context of education: National Forum on Education Statistics. (2010). Forum Guide to Data Ethics (NFES 2010–801). U.S. Department of Education. Washington, DC: National Center for Education Statistics. <http://nces.ed.gov/pubs2010/2010801.pdf>
There are many similarities.

Genomic information, however, has a special place in our thinking because of the issue of disclosure of potentially life threatening, serious health outcome information that may need to occur in the context of an at-risk family. The ethical principle of respect that includes the value of autonomy is problematic in this setting. In Australia we have developed a section in the Privacy Act that attempts to deal with this in the health care setting, but which may be applied more broadly: See <http://www.nhmrc.gov.au/files/nhmrc/publications/attachments/e96.pdf>

An ethical issue that remains unmentioned in all of this is the potential use and therefore production of inaccurate results through use of large data sets from multiple sources without standardised, validated approaches to actual data collection and analysis. In addition, there is the possibility of people opting out/not providing consent to be included in a particular dataset that then leads to selective bias, incomplete data. It is well recognised that unintended, even nonsensical, input data ("garbage in") produces undesired, often nonsensical, output ("garbage out"). (Adapted from wikipedia)

Data handlers are ethically responsible for knowing the laws, regulations, and policies that govern access to the information for which they are responsible ... (and) they are ethically responsible for ensuring high data quality to the best of their ability. ((Adapted from: National Forum on Education Statistics. (2010). Forum Guide to Data Ethics (NFES 2010–801). U.S. Department of Education. Washington, DC: National Center for Education Statistics. <http://nces.ed.gov/pubs2010/2010801.pdf> (page 21))

I hope this is of some help and am impressed by the depth of thought that has already gone into the whole topic.

I have attached the pages with my details as I will be very interested to see the final report

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