Author’s response to reviews

Title: DNA Databanks and Consent: A suggested policy option involving an authorization model

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PDF covering letter
Dear Sir:

We would like to thank our peer reviewers for the comments and suggestions, and their time and effort spent reviewing this manuscript. Their efforts are greatly appreciated. As Professor Williams has no substantial criticisms, we will thank her for her time and move to the substantial comments raised by Professor Richard Sharp in his reviewer’s report. We thank him for his penetrating insights and deep reading and will respond to the points he makes in the following letter, as well as to point out the changes we have made to the manuscript in response to his comments.

We found the comments from Professor Sharp helpful and challenging. The intention of this paper is not to review consent law in its entirety, or to summarize the available empirical data on public opinion regarding the consent process for genetic research. This relates to comments 1) and 2). Rather, the paper has a rather narrow focus as stated in the last paragraph of the introduction. In other words, this paper is not devoted to the issues related to existing biological samples and their genetic analysis but to the creation and development of genetic databases that are being created and developed prospectively. In this context, it is quite clear that there will be future uses for this data that will be linked to personal health information that is also collected, and that the existence of the full range of research questions that will be posed in such large databases such as the UK Biobank, can be considered ineffable at this time, and thus fully informed consent is not available. It is within this context that we are working. That said, we will do our best to address some of Professor Sharp’s concerns.

For comment no. 1, Professor Sharp suggests that we review available empirical data on public perceptions of the consent process. This is an interesting point as there are many useful studies available. A comprehensive review of this work requires substantial elaboration and would be a different paper than the one intended here. Indeed, Professor Caulfield has recently submitted a paper reviewing available empirical data entitled “DNA databanks: public opinion and the law”. However, in this specific paper we do not make explicit reference to the need for research on consent, as suggested by Professor Sharp, though we do agree this is a good idea. Rather, research is required looking at the tradeoffs involved in an authorization model is required. As such, it is hard to determine what is at the bottom of this criticism. Nevertheless, our paper could only benefit from
the inclusion of a few additional references on this point. Therefore, we have added text and references; please see the end of the second paragraph in the policy option section.

Regarding comment no. 2, the reviewer would like us to review consent standards with more precision and how they have evolved, as he feels we have not established that this obligation is onerous. Again, this is an interesting suggestion that would take a great deal of elaboration to address thoroughly. As noted by Professor Sharp, the specifics of consent law vary significantly between jurisdictions. Given the brevity of our article, we believe we do a reasonably good job of explaining the history and the general nature of the legal obligation. We have commenced with highlighting the Nuremberg code that current consent laws in the research setting is the most exacting duty possible, and the general nature and source of the consent obligation. However, we believe it is a truism that the consent obligation in the research setting is quite onerous and that few readers would dispute this point. However, to address this reviewer’s concern, we have added the following information. We have made an amendment in the first paragraph of the informed consent section.

Comment no. 3 is related to comment no. 2. Specifically, the reviewer would like us to support the suggestion that obtaining consent for databanks would be tremendously onerous, and that there is no way to predict future uses. Here we believe we have a fundamental difference with the reviewer. Indeed, we believe that both claims are widely accepted. Both of these points have motivated a great deal of policy work on the topic.

We cite the recent UK human genetics commission report, thus the difficulties involved “in tracing and securing reconsent for different forms of medical research may make obtaining fresh consent impractical and would seriously limit the usefulness of large-scale population databases”. We also cite the UNESCO Draft Report on collection, treatment and storage of use of genetic data. There may be disagreement from Professor Sharp, but we believe that these two points are at the heart of much of recent debates regarding the creation of population-based DNA databases. We could provide more information regarding these two issues, but we believe we have covered this sufficiently.

With regard to comment no. 4, we are unsure of this criticism. We do not contend that the strength of our authorization model is that it would increase control. On the contrary, it provides the possibility of less control than current informed consent standards, and therefore it raises the issue and need for other safeguards. We think that individual control or autonomy driven consent is a fundamental principle in health law and research ethics. This is at the base of much of the debate and we believe we do not need to re-argue this point. We have an entire paragraph on why consent may be particularly important in this context. Professor Sharp also suggests that additional safeguards such as legislation may be needed. We completely agree and have, in fact, pointed out the need for additional safeguards to bolster any change to the consent process to an authorization model. We note the need for either a data ombudsperson, the involvement of institutional review boards, as well as legislative oversight to change this.
Comment no. 5 – we believe that we have sufficiently distinguished our position from that of a blanket consent model. It is similar in some respects to a blanket consent but the primary difference is conceptual. The conceptual difference is important because it forces policy-makers in the public to recognize that true informed consent in the context of a population-based prospective large-linked database is likely impossible and that certain fundamental rights may be lost and that additional safeguards may be necessary. As we note in the beginning, the goal of this paper is to highlight the nature of this policy issue. The important issue here is that the concepts such as blanket consent or presumed consent strain the nature and language of consent, which is precise and clearly understood, and in our view such modifications to the concept of consent threaten its legitimacy and undermine it conceptually. We have specified the many ways in which authorization differs from blanket consent. The traditional blanket consent is a one off signature with no further involvement at the research process. The authorization model provides a range of possibilities, and if certain individuals are inclined towards blanket consent, they have the possibility of exercising that option. However, blanket consent is not presumed to be satisfactory to all individuals, particularly those who may wish to have more ongoing involvement with the genetic databank. In this respect, we have cited the article by Beskow and others that Professor Sharp claims we have neglected, (and we should note that in this paper they have made the argument not to involve participants any further in communicating research results back to them). Therefore, we believe there is a fundamental difference between an authorization model, which opens up and holds the possibility that certain research subjects may have continuous ongoing involvement with the project, and others may wish not to. We believe this is a substantial step forward and is quite different from models of blanket consent.

With respect to comment no. 6, we believe Professor Sharp begs the question on this. The point of our paper is not to consider a proxy. We find this problematic, the introduction of proxies, particularly when competent adults are available to exercise their preferences. Secondly, the premise of our paper is precisely on the existence of future sample uses of genetic material that are unforeseen at initial collection and that is the point of achieving pre-authorization for some of these uses, or having a process of reciprocal involvement.

Finally, for point 7, Professor Sharp expresses surprise that we have not referred to prior work in the area. Given that we have, in fact, cited the work of Beskow, the UNESCO statements on genetic research and some of the work by Greely, we believe that we have cited many of the authors that he requests. This is not meant to be a systematic review of every article written on ethical issues in population genetics. However, we have bolstered up our references in the initial paragraph, and will include the manual and their paper as well as the NBAC document.
Again, we thank Professor Sharp for his penetrating comments. We believe we have answered or made amendments to most of the criticisms made by Professor Sharp. As some of these involve legitimate scholarly disagreement, we believe this just highlights the nature of the issues involved in our paper, which makes a compelling case for it to be available for the greater scholarly public to reflect upon. We thank you for your time and efforts with this manuscript, and look forward to hearing an editorial decision.

Sincerely yours,

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