Database Research: Public and Private Interests

VILHJÁLMUR ÁRNASON

Introduction

It is often argued that a major tension in bioethics is between protecting the private interests of individuals on one hand and contributing to the common good on the other. In this article I ask how fitting this description is as regards the interest at stake in relation to the issue of consent to participation in population data collections. I raise some doubts about what I take to be two common positions regarding public and private interests in this context. The first is that restricted individual consent protects private interests at the cost of public interest. The second is that broad, unrestricted consent, while placing less emphasis on individual rights, is likely to serve common interests. I argue that both these positions are misleading and that they share the common shortcomings of regarding the citizen in a passive role. I introduce a notion of scientific citizenship in which private and public interests are entwined in such a way that they are not clearly separated. It becomes a matter of public interest to look for ways to increase and sustain the scientific awareness and literacy of each individual. This requires that we look for new kinds of ways to preserve the ethos of meaningful voluntary consent in population research. I point toward some ways to work in the spirit of this vision and consider two objections to it.

When I talk about databanks in this paper, I have in mind human genetic databases that combine health data and genetic data (and sometimes genealogical data) from a large population. These population databases are resources for genetic research on various diseases but have not been built up in the context of healthcare.[1]

Restricted Consent and Private Interests

In the WHO report (2003) on genetic databases, the following clause is to be found:

> We have, then, a fundamental tension between the possibility of considerable public good on the one hand, and the potential for significant individual and familial harm on the other. The basic interests that lie in the balance are those between human dignity and human rights as against public health, scientific progress and commercial interests in a free market.[2]

I choose this passage as a typical representative of broadly accepted views regarding tension between private and public interests in the handling of genetic information in population genetic databases. The interests related to the private

Cambridge Quarterly of Healthcare Ethics (2011), **20**, 563–571.
© Cambridge University Press 2011.
doi:10.1017/S0963180111000302

https://doi.org/10.1017/S0963180111000302 Published online by Cambridge University Press

sphere are described in terms of human dignity and individual human rights, while the public interests are identified as various kinds of social and scientific benefits. I am particularly interested in how these may relate to the question of consent for participation in population database research and the arguments for restricted or unrestricted consent for such research.

Is restricted consent for participation in population database research likely to protect important individual interests related to dignity and human rights? To answer this question, it is useful to draw on the distinction between welfarist reasons and autonomy reasons for seeking informed consent for research.[3] Welfarist reasons include considerations such as protection against unnecessary risk, including violation of privacy, and assurance that the research participant is not being exploited. These considerations would clearly weigh in favor of not abandoning consent based on general information about the conditions for the use of data donated for research in a population databank and about how supervisory institutions protect participants' interests. These are also good reasons for giving participants the option not to participate in particular research projects that would require that they be kept informed about the research activities of the database. None of these, however, require a policy of restricted informed consent for each particular research project carried out in the database. To the contrary, from a welfarist point of view such practice can be seen as a disadvantage for the participants, who are likely to be bothered by continuous re-contact.[4] Moreover, such a policy of restricted informed consent is likely to reduce participation in database research, resulting in a loss of scientific value, which is the main reason for most participants to donate in the first place.

Are there strong autonomy reasons for obtaining restricted informed consent for participation in database research? This question requires that we evaluate the autonomy-enhancing features themselves in this context rather than whether established rules for protecting autonomy may be relaxed due to important benefits. I partly agree with Tuija Takala when she writes that the benefits of genetics are largely uncertain:

> With all these uncertainties, I see very few reasons for relaxing the rules of consent in the context of genetics. It has taken us a long time to get where we are now in terms of ethics, and especially in terms of individual human rights, and if we want to stay on this path we should not let the ambiguous promises of science lead us astray.[5]

I will leave the discussion about the possible benefits of database research to the next section. The question here is rather whether "this path" that we are on "now in terms of ethics" is appropriate as regards consent for participation in population database research.

In practice, the path is the one of informed consent, which is plagued by several well-known problems in this context. The first problem I call the routine problem, which implies that rather than genuinely informing participants, the research organizers tend to simply ask the participants to sign informed consent forms, which then counts as a justification for carrying out the research. This is partly because the dialogical conditions that are necessary to facilitate informed consent are largely lacking in the context of obtaining consent for participation in population genetic databases. But this act of signing does not imply genuine consent, which leads to the problem of understanding: the more information that

https://doi.org/10.1017/S0963180111000302 Published online by Cambridge University Press

is provided, the less participants understand. Both these problems are problems of justification. As Onora O'Neill has argued, "consent achieved by overwhelming an agent's cognitive capacities provides no genuine justification."[6] If the standards of genuine informed consent cannot be met while the practice of research is justified by it, the result will be "systematic hypocrisy."[7]

What are the moral values that are to be protected by informed consent? It could be argued, for example, on the basis of the Belmont Report, that the moral objective of informed consent is to provide participants with opportunities for personal deliberation, which underpins considered judgment.[8] As we have seen, this is unrealistic, at least as regards population database research. A more simple and realistic answer to the question of what should be protected by consent for research participation involves the requirements of non-coercion and non-deception. I take these requirements as the main principles for preserving the conditions for agency, which is of crucial interest to human beings. In light of the problems of informed consent that I have discussed, there are no good reasons to believe that this interest in agency is well served by restricted individual consent. This interest could be served better by a broader, initially clear consent to the conditions of use of the information donated for research, coupled with the possibility of being kept informed about the research practices in the database, which gives subjects the option to withdraw from a research project. This, however, requires some kind of general authorization when the data are collected, but it does not require a restricted informed consent tied to a particular research project, as described previously in the spirit of article 22 of the Helsinki Declaration, with the potential of bothering participants with continuous re-contact.[9]

Open Consent and Public Interest

By an open consent I mean in this context that participants in database research agree that their data will be used for any future scientific research permitted by the supervisory institutions. The main emphasis is thus laid on deliberation and scrutiny of research protocols by the overseeing committees that evaluate the participants' interests and act on their behalf. This is indicative of the trend to regard genetic data collections as major resources to be mined for the benefit of society without the interference of the participating individuals, who should simply trust regulating institutions to take care of their interests.

Whereas the emphasis on restricted informed consent reflects liberal emphasis on individual rights, the emphasis on open consent has both communitarian and utilitarian flavors, depending on how the arguments are formulated. A utilitarian argument could be that the public interest is best served by mining the data resource in an efficient way for drug development and other medical benefits. In communitarian language, these can be called goods that we can create only in common and not in atomistic isolation.[10] From this viewpoint, the emphasis should be on the duties of participants to contribute to progress in medicine and science no less than on having their individual rights protected.

To deal with the question of whether an open consent is conducive to public interest, we need to consider what kind of benefits can reasonably be expected to be reaped from population database research. When we consider possible advantages of genetic data collections for society, we need to distinguish between

https://doi.org/10.1017/S0963180111000302 Published online by Cambridge University Press

at least two types of possible welfare benefits: non-health-related welfare benefits and health-related welfare benefits. Examples of the former are increased employment opportunities for young scientists and the possible general social benefits of having a thriving research company in genetics and information technology in the community. Although these things are closely related in the minds of politicians, they can possibly be created in other research fields that would not require genetic data collections.

Arguments for genetic data collections have been characterized by the possible health-related welfare benefits; the primary purpose of population genetic databases is "to search for susceptibility genes for complex diseases while attempting to improve public health and medical care."[11] Strong statements, both by scientists and politicians, have been made about the potentials of this "promissory science" for healthcare.[12] In a deCODE Genetics company profile from 2003, the main promises of benefits are the following:

> The new genetics promises to transform the practice of medicine by enabling physicians to assess the risks of disease, permit early detection of disease, determine likely responses to medication, choose the best courses of therapy and have at their disposal new therapies that target the disease process itself. deCODE is focused on turning its uniquely powerful capabilities into valuable new products for the market.[13]

Regardless of how likely these promises are to come true—this likelihood is partly an empirical question that remains to be answered and partly a controversial matter of benefit evaluation—it is interesting to see what kind of promises these are and which social implications they might have. The key notion in the deCODE promises is "to transform the practice of medicine," and it is appropriate to ask in this context whether this transformation would be beneficial to society. Let us take a brief look at the first two of the promises mentioned in the passage. (The third promise is possibly the strongest candidate for benefits, but it has been widely discussed and will be left out here.)[14]

The promise of enabling physicians to assess the risks of disease relates to the goal of initiating preventive measures for the individuals who are found to be at increased risk. Although this may in many cases be of benefit to individuals, the social benefits of such knowledge would be increased if it could be combined with knowledge of behavioral and environmental risk factors in the formation and penetration of disease.[15] If the focus is limited to genetic risk of disease, the emphasis is on individual responsibility, rather than, for example, on improvement in people's working conditions. This transformation of the practice of medicine could therefore lead to a transfer of emphasis from social determinants of health, for which we are jointly responsible, to individuals controlling their own risk of developing disease. Such a change is unlikely to serve the public interest.

The promise regarding early detection of disease has been widely discussed, for example, in relation to genetic counseling, and the benefits of this are clearly dependent on whether therapies are available for the disease in question.[16] To be sure, people can use knowledge of an incurable disease to change their lifestyle and prepare for the onset of the disease, but it is debatable whether large genetic data collections are necessary for such detection. Often, people are aware from their family histories that they are susceptible to certain diseases, and it is

https://doi.org/10.1017/S0963180111000302 Published online by Cambridge University Press

questionable whether technologically demanding scientific research and expensive genetic testing are needed to certify that information. Moreover, such certification can trigger premature physical and psychological distress, as has been discussed in the literature about medicalization.[17]

The company deCODE Genetics has been conducting population genetic research since 1998. It is a flourishing research company in the sense that it has a strong team of scientists who have a remarkable publishing record. When the company was being introduced, the main message, however, was focused on the health-related products and benefits that it would produce, as is reflected in the company profile. In light of this, it is somewhat ironic that the most notable product of the company so far is the online direct-to-consumer service, deCODEme, a test for genetic susceptibility to various diseases. On the company website, customers are invited to discover their genetic risk for 47 medical conditions.[18]

The main criticism of this direct-to-consumer service is that the clinical validity and clinical utility of most of these tests has not been well established.[19] There is also criticism that the lack of professional counseling in relation to these tests makes it very difficult for laypersons to gain meaningful results. On the website of deCODEme, there is the following clause: ''We help you to interpret your results and show you how they relate to your health. View them online, contact one of our experts or share your results with your physician.'' The last point about sharing these results with a physician may have consequences that could undermine the public good: ''This might prompt doctors to refer people for research which no reliable scientific knowledge shows to be justifiable. This would increase the burden on our public health service . . . and it is unlikely that this would deliver results in terms of better health for the individual.''[20]

I conclude from this brief discussion that the public benefits to be reaped from population database research are still largely uncertain. It remains unclear as to how the scientific knowledge produced will be translated into medicine, and it is also debatable whether that possible transformation of medicine would be beneficial to the general public. The intrinsic value of scientific knowledge should not be underestimated, but it is not a sufficient reason for implementing a policy of open consent in order to increase the flexibility of the researchers, unless there are no other important public concerns to be protected. But I believe there are such concerns and that they have been largely neglected.

Consent and the Democratic Ethos

In discussions about interests related to the issue of consent to participation in population database research, it often appears that the alternatives are primarily between a liberal emphasis on individual rights and a communitarian emphasis on collective interests. This dichotomy is indirectly reflected in the discussion about restricted informed consent that presumably protects individual interests and unrestricted consent that presumably furthers public interests. As I have tried to show previously, this is misleading in the sense that it is unclear either that (1) restricted informed consent protects important private interests or (2) that unrestricted consent will facilitate important public interests. I now try to show that each of these positions, in its own way, tends to neglect crucial public interests that relate to the interest in democratic agency and awareness.

https://doi.org/10.1017/S0963180111000302 Published online by Cambridge University Press

As I have argued elsewhere, from this viewpoint, these apparently opposing positions, in fact, have more important things in common than they do things that divide them.[21] By focusing primarily on protecting participants from violations of privacy, harm, and discrimination, or on mining the population for maximum benefit, they are similar in viewing the citizen in a passive role. They provide no reasons for addressing people as active and reflective citizens in democratic society. This is rather obvious in the case of the open consent policy, in which all deliberation about population research participation would be transferred to supervisory bodies. In so doing, the interest in maintaining a reflective and informed citizenry, which is crucial from a democratic perspective, is sacrificed for public interest related to increased scientific knowledge and possible but uncertain and controversial social benefits.

The picture is more complicated in the case of restricted informed consent, which, at least in principle, invites opportunities for personal deliberation. But if my preceding argument—that the interest in agency is better served by a broader initial consent, coupled with the right to withdraw from any particular research project—is valid, we see this in a different perspective. From a democratic point of view, this interest in agency is not well served unless there are ways to enable the participants both to be more active themselves in following the path of the research performed in the database and to motivate the regulatory institutions to be more accountable. Both these aspects are captured in the following passage by Onora O'Neill:

> [T]rustworthy institutions will have to incorporate user-friendly ways by which individuals can check whether what is done to the data they consent to make available accords both with publicly agreed systems of data protection and with the content of the consent that they have given. Checking procedures need to be ready to hand and easily useable, although they will rarely be used if they successfully create trust.[22]

There are a few preconditions for the policy suggested in this highly interesting and important proposal. First, there is what relates to the ''publicly agreed systems of data protection.'' This takes place on the political level and requires informed public debate and professional work. This could best be done in the spirit of deliberative democratic theory, which ''critically investigates the quality, substance, and rationality of the arguments and reasons brought to defend policy and law. It studies and evaluates the institutions, forums and venues, and public spaces available for deliberative justification and accountability.''[23] This envisions engaging the citizens in societal dialogue before general policies are implemented. An informed democratic consent that would be reached in this way would, however, not replace, but at best complement, individual consent for participation in database projects. This relates to the part in the previously quoted passage where O'Neill speaks about enabling participants to check whether what is done accords with ''the content of the consent that they have given.''

Both of these aspects can be seen as arguments for active scientific citizenship that moves beyond the important objectives of individual protection and public benefits without giving them up. This is done both by emphasizing the importance of creating the conditions for an informed societal dialogue about the general systems of regulation and policies in relation to population databanks

https://doi.org/10.1017/S0963180111000302 Published online by Cambridge University Press

and by facilitating conditions for the individual participants to keep themselves informed about the pattern of research conducted on the information they have donated to such databanks. This I believe will better serve the major moral objectives of non-coercion and non-domination than alternative polices. It is important not to limit these conditions to the voluntary sphere of individual action and reflection. We also need to place this in the context of political decisionmaking, which shapes the context against which the individuals make up their mind and exercise their deliberative capacities and "moral powers," as Rawls calls them.[24]

How can the search for ethical frameworks be enlightened by the vision of the "active, informed, reflective and responsive citizen"?[25] It is crucial that this be seen in terms of shaping conditions that enhance scientific literacy and awareness of the social implications of biotechnology and genetic research. This is a task that needs to be undertaken at several levels of society. First, educational programs need to be developed aimed at increasing scientific literacy, social awareness, and critical thinking about science and technology. Second, the scientific media needs to be strengthened so that citizens are kept better informed about scientific projects and their social implications. Third, this vision requires transparency and professionalism in the work of supervisory agencies, which also need to be creative in finding ways to enable participants in population database projects to follow the research and, with continuous information, to exercise their consent and their right to opt out of particular research projects if they so choose. Finally, there is a need to create deliberative public forums that enable citizens to inform themselves about scientific projects, exercise their reflective capacity, adopt a public standpoint, and influence policymaking.

I end by considering briefly two objections, liberal and practical, to the idea of scientific citizenship in the spirit of deliberative democratic theory. The liberal criticism of the deliberative vision of the citizen concerns the demands placed on the citizens in liberal democratic society. This objection need not doubt the intrinsic value of deliberation; rather, it would emphasize other values that are more important to protecting people's basic interests. If one would take the deliberative vision of citizenship to emphasize public participation over protection of basic interest, this objection would certainly apply. But public accountability is the basic requirement of the democratic legitimacy of a policy. This implies that the policy needs to be justified to everyone whom it affects and that the policy would be accepted in an informed and unrestrained public dialogue.

More generally, it could be stated from the viewpoint of liberal neutrality that the citizens should enjoy their right to non-interference and should not be bothered with demands for collective deliberation on public policy.[26] They should legitimately be able to enjoy the privacy of their personal life and have freedom from politics. The deliberative vision of the scientific citizen does not question the right to privacy and freedom from politics, but it emphasizes the fact that in a democratic society every citizen is partially responsible for public policy. It is a duty of democratic politicians to conduct politics in such a way that citizens are well informed and otherwise enabled to assume their responsibilities as free and equal citizens, which in turn should affect political decisions. It could still be said that many citizens are not interested in being informed and responsible, and their choices in that regard will be respected. Nevertheless, it is quite compatible

https://doi.org/10.1017/S0963180111000302 Published online by Cambridge University Press

with liberal politics to emphasize citizenship education that motivates citizens to think about common concerns and to develop reasoning skills, along with mutual respect, that are crucial for deliberative democratic practices.

The practical criticism of the deliberative vision of the scientific citizen need not doubt any of the theoretical tenets; rather, it points to the complexities and obstacles to be dealt with in relation to its implementation. There are several issues involved, not least of which is the attempt to create forums and public spaces for deliberative accountability and participation. Social scientists have probed these issues with interesting questions: How can meaningful engagement of the public be facilitated?[27] What sort of information is provided, and how should it be presented to the public? How are issues to be framed for public debate?[28] How is public consultation to be institutionally located, and are there ways to ensure that it will inform government policy? As has been well stated, "it is necessary to adopt a flexible and situationally appropriate approach" rather than a one-size-fits-all model of deliberative practices.[29]

It is important to take realistic reservations into account. However, most importantly, from the perspective of this article, public policy about biotechnology should be guided by a vision that provides democratic resistance to the social engineering and passive formation of the citizen. In a democratic society, the interest in enhancing these aspects of citizenship is at the same time public and private. The citizen is not (only) a private person; citizens must "regard themselves as being entitled to make claims on their institutions so as to advance their conceptions of the good."[30] If the task is regarded as maintaining and creating the conditions for keeping "the moral powers" of citizens active and respected, we may see that the ethos of democratic culture is at stake.

Notes

1. Cf. Árnason G. On human genetic databases. In: Häyry M, Chadwick R, Árnason V, Árnason G, eds. *The Ethics and Governance of Human Genetic Databases: European Perspectives.* Cambridge: Cambridge University Press; 2007:11–3.
2. World Health Organization. *Genetic Databases: Assessing the Benefits and the Impact on Human and Patient Rights. European Partnership on Patients' Rights and Citizens' Empowerment*. Geneva: WHO; 2003:3; available at www.codex.vr.se/texts/whofinalreport.rtf (last accessed 27 Jan 2011).
3. Kristinsson S, Árnason V. Informed consent and human genetic database research. In: Häyry M, Chadwick R, Árnason V, Árnason G, eds. *The Ethics and Governance of Human Genetic Databases: European Perspectives*. Cambridge: Cambridge University Press; 2007:199–216.
4. Cf. Hoeyer K, Mjörndal T, Olofsson BO, Lynöe N. Informed consent and biobanks: A population-based study of attitudes towards tissue donation for genetic research. *Scandinavian Journal of Public Health* 2004;32:224–9.
5. Takala T. Why we should not relax ethical rules in the age of genetics. In: Árnason G, Nordal S, Árnason V, eds. *Blood and Data: Ethical, Legal and Social Aspects of Human Genetic Databases*. Reykjavik: University of Iceland Press; 2004:135–40, at 139–40.
6. O'Neill O. Informed consent and genetic information. *Studies in the History and Philosophy of Biological and Biomedical Sciences* 2001;32:689–704, at 701.
7. Manson NC, O'Neill O. *Rethinking Informed Consent in Bioethics*. Cambridge: Cambridge University Press; 2007:25.
8. Kristinsson K. The Belmont Report's misleading conception of autonomy. *Virtual Mentor. American Medical Association Journal of Ethics* 2009;11:611–6.
9. Cf. Greely H. Breaking the stalemate: A prospective regulatory framework for unforeseen research uses of human tissue samples and health information. *Wake Forest Law Review* 1999;34:737–66; Caulfield T, Upshur REG, Daar A. DNA databanks and consent: A suggested policy option involving an authorization model. *BMC Medical Ethics* 2003:4; available at http://www.

https://doi.org/10.1017/S0963180111000302 Published online by Cambridge University Press

biomedcentral.com/1472-6939/4/1 (last accessed 27 Jan 2011); Árnason V. Coding and consent. Moral complications of the Icelandic database project. *Bioethics* 2004;18:39–61; Kaye J. Broad consent — the only option for population genetic databases. In: Árnason G, Nordal S, Árnason V, eds. *Blood and Data: Ethical, Legal and Social Aspects of Human Genetic Databases*. Reykjavik: University of Iceland Press; 2004:103–9.
10. Cf. Sandel M. *Liberalism and the Limits of Justice*. Cambridge: Cambridge University Press; 1982.
11. Austin MA, Harding S, McElroy C. Genebanks: A comparison of eight international genetic databases. *Community Genetics* 2003;6:37–45, at 42.
12. Hedgecoe A. *The Politics of Personalized Medicine: Pharmacogenetics in the Clinic*. Cambridge: Cambridge University Press; 2004:16–17.
13. Hakonarson H, Gulcher JR, Stefansson K. deCODE Genetics Inc. company profile. *Pharmacogenomics* 2003;4:1–7, at 7.
14. Cf. Smart A, Martin P, Parker M. Tailored medicine: Whom will it fit? The ethics of patient and disease stratification. *Bioethics* 2004;18:322–42.
15. Halliday JL, Collins VR, Aitken MA, Richards MPM, Olsson CA. Genetics and public health—evolution or revolution? *Journal of Epidemiology and Community Health* 2004;58:894–9.
16. See, for example, Ost D. The ''right'' not to know. *Journal of Medicine and Philosophy* 1984;9:301–12.
17. See, for example, Press N, Fishman JR, Koenig BA. Collective fear, individualized risk: The social and cultural context of genetic testing for breast cancer. *Nursing Ethics* 2000;7:237–49.
18. www.decodeme.com/genes-and-health (last accessed 21 Jan 2011).
19. For a short overview, see Stefánsdóttir Á. The sale of genetic information: Ethical aspect of genetic analysis. In: Tupesala A, ed. *Consumer Medicine*. Copenhagen: Nordic Council; 2010:27–38.
20. See note 19, Stefánsdóttir 2010, at 35.
21. Árnason V. Scientific citizenship, benefit, and protection in population based research. In: Solbakk JH, Holm S, Hoffman B, eds. *Ethics of Research Biobanking*. Dordrecht: Springer Verlag; 2009:131–41.
22. See note 6, O'Neill 2001, at 702.
23. Chambers S. Deliberative democratic theory. *Annual Review of Political Science* 2003;6:307–26, at 309.
24. Rawls J. Justice as fairness: A restatement. In: Kelly E, ed. Cambridge (MA): Harvard University Press; 2001:18–24.
25. Crick B. *Education for Citizenship and the Teaching of Democracy in Schools: Final Report of the Advisory Group on Citizenship*. London: Qualifications and Curriculum Authority; 1998:9.
26. Cf. Kristinsson S. Autonomy and informed consent. A mistaken association. *Medicine, Health Care and Philosophy* 2007;10:253–64.
27. Powell MC, Colin M. Meaningful citizen engagement in science and technology: What would it really take? *Science Communication* 2008;30:126–36.
28. Felt U, Fochler M, Müller A, Strassnig M. Unruly ethics: On the difficulties of a bottom-up approach in ethics in the field of genomics. *Public Understanding of Science* 2009;18:354–71.
29. Irwin A. Constructing the scientific citizen: Science and democracy in the biosciences. *Public Understanding of Science* 2001;10:1–18, at 16.
30. See note 24, Rawls 2001:23.

https://doi.org/10.1017/S0963180111000302 Published online by Cambridge University Press