Scientific Citizenship, Benefit, and Protection in Population-Based Research

Vilhjálmur Árnason

Abstract In the discussion of ethical issues concerning databases as resources for population research, two main positions have been predominant. On the one hand, a major emphasis has been on protecting the participants from being discriminated against or having their privacy violated. The other main emphasis has been on the substantial benefits that can be reaped from the research. I show how these often conflicting positions share an important underlying and hidden presumption, implying a too narrow vision of the citizen as a passive participant. I argue that it is important to explore alternative visions of the citizens in relation to population database research. For this purpose, I ask whether recent ideas of deliberative democracy and scientific citizenship provide us with a viable guiding vision of how to facilitate a more active and informed public engagement in database research society. I flesh out my ideas in terms of the debate about consent for participation in database research and show how different models of consent imply different visions of the citizen. I argue that a dynamic authorization model with an opt-out clause could contribute to conditions for more informed, active and critically aware citizens.

Introduction

Biopolitics and bioethical discourse implicitly reflect visions of the citizens that play a major role in policies about scientific research and biotechnology. These views resonate with general positions about the major functions of democracy and about the nature of citizenship. In this chapter, I first describe two typical views or ideal types of the citizen that I take to be prevailing in social and theoretical discourse about bioethical issues. I call them the protective view and the benefit view. I then explore an additional vision of the citizen which has been largely ignored but has more

V. Árnason
Department of Philosophy and Centre for Ethics, University of Iceland, Reykjavik, Iceland
e-mail: vilhjarn@hi.is

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active democratic features than the other two. I flesh out these views by showing how they have been made manifest in ideas about consent for population databases and biobank research. I also aim to show what implications they have for a broader social debate about biopolicy.

Since my reflection on these issues has mainly been inspired by the Icelandic experience I will draw my examples from there. This experience has been widely discussed (e.g. Greely 2000; Rose 2001; Árnason 2004). The dominating emphasis in the Icelandic discussion concerning participants' interests has been on privacy. The focus was mainly on two kinds of technical issues, a legal technicality about personal identifiability and coding techniques for storing the information (Gulcher and Stefánsson 2000). Privacy protection is certainly important from a moral point of view since personal data should not get into the hands of insurance companies, employers or others that could be motivated to use them for discriminatory purposes. But it is very limited to evaluate the interests of people mainly, not to say exclusively, from this perspective. There is a reason to believe that the extensive discussion about these matters precluded reflection on issues relating to active human agency, for example of consent and informed public debate.

Protecting Participants

The strong emphasis on security in the Icelandic discussion about the Health Sector database exemplifies what I call the *protective view* towards citizens. The view draws its name from the fact that either explicitly or implicitly the ethical regulation of biotechnology and research on humans emphasize above all the *protection* of people. Some of the major moral objectives in research ethics are protection of privacy, protection against risks (participants' welfare) and protection of vulnerable research subjects (a major requirement of justice). In all these cases, measures are to be taken that safeguard research participants and citizens in general from the possible hazards of biotechnology and misuse of information. Protection of autonomy is a more complicated matter but as it is usually fleshed out in the requirement of informed consent it tends to be reduced to a formal procedure which poses little or no challenge to the participant as an active, reflective agent. Moreover, such a narrow notion of autonomy can serve a questionable legitimizing function far beyond its scope (Árnason and Hjörleifsson 2007).

If we relate this to ideas of democracy, we see that these requirements of security and protection fit well with the function of liberal democracy to protect citizens against the misuse of both state power and marketing forces. This most often translates into the right of the citizens whose "private domain" needs to be protected against the invasion of powers that can manipulate people and make use of personal information in a discriminating way. This also squares well with the corresponding notion of citizenship which is seen in terms of the citizen as a bearer of basic civil rights (Marshall 1950). In the national debate about the Icelandic Health Sector Database case, an organization was formed with the particular objective of

protecting the rights of citizens against both the misuse of public authority and a powerful private company, largely driven by market forces. Appropriately, the association is called "Mannvernd" in Icelandic, literally "human protection" which resonates well with "Persónuvernd", the name of the Icelandic Data Protection Agency.

It is instructive to see how the protective view made itself manifest in the debate about what kind of consent should be required for the Icelandic Health Sector Database. Some scholars criticized the plan for "lack of informed consent" (Greely 2000). Spokesmen of Mannvernd were among the hardest critics of the deCODE project and demanded informed individual consent. As can be seen from the homepage of the association, www.mannvernd.is/english/, this demand has often been supported by appealing to basic principles of research ethics or has even been put forth as a human right. However, this appeal to individual rights has also been used strategically by activist opponents of commercialized database research.

Specific consent implies that participants will be informed prior to donating their samples or data for research about its objectives, risks, benefits and other traditional ingredients of informed consent. A major problem with specific informed consent in this context is that it is unsuitable for multi-disease research on genetic collections. If data are collected for a particular research and no research can be carried out on the data that was not specified in the consent form, then any research with new questions requires re-contact with the participants. Participants find such continuous re-contact annoying and experience has shown that they are willing to give a wider consent and leave it up to the researchers and the regulatory committees to ensure that they are used fairly for the benefit of science and society (Hoeyer et al. 2004).

It could be argued that one of the important functions of informed consent is to protect people's well-being through their increased awareness of risk and their control of their research partiticipation. However, in the context of biobank research these important benefits will be better secured by other means than specific informed consent. Such consent requires detailed descriptions in scientific protocols which tend to overwhelm participants' intellectual capacity. The paradox is that the more information is provided, the less understanding is obtained, and the consent procedure becomes a mere formality. Instead of maximizing options for individual deliberation and control, opportunities for deliberation are actually lost in this way and the interest in human agency is not well served.

Benefiting Participants

The protective view, especially in relation to the issue of consent, has been partly in tension with a position which I label the benefit view. The reason for using this label is that here the emphasis is on the *benefits* that can be reaped from biotechnology and genetic research. These benefits can be either health-related, such as drug development, more effective predictive and preventive medicine, or benefits unrelated to health, such as increased employment opportunities for young scientists and

other social and economic advantages that may flow from having thriving research companies. This medical and social utility position has been prevailing in political and economic discourse about biotechnology.

It is understandable that researchers reject specific individual consent for database and biobank research and prefer a version of an open consent. By an open consent is meant here that participants agree that their data will be used for any future scientific research permitted by the regulatory institutions. The main emphasis is thus laid upon institutional trust, such as trust in research ethics committees which would evaluate the participants' interests and act (as surrogates) 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. In this way the benefit view lends itself to an open consent.

The emphasis on open consent has both communitarian and utilitarian flavours, depending on how the arguments are formulated. A utilitarian argument could be that public interests are best served by mining the data resource in an efficient way for drug development and other medical benefits. The Icelandic parliamentary discussion clearly had such a utilitarian tone which was increased by reference to additional advantages, such as increased employment opportunities for young scientists. There was also a strong appeal in the discussion to the national genome and medical records as social resources that should be exploited for the common good. In communitarian language, these can be called goods that we can only create in common and not in atomistic isolation (Sandel 1982). 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 privacy rights protected.

It can be argued that the benefit view towards biotechnology relates to the function of welfare democracy of ensuring that decisions are made in the collective interests and to further the common good. It also relates to the view on citizenship which emphasizes social and economic rights to security. In fact, this argument from collective interests is often used to accuse the protective position of emphasizing individual rights at the expense of social goods. This argument can be met from two angles. First, many of the social benefits that are promised by genetic population research are both debatable and uncertain. Moreover, even though they would bring benefits to the wealthier part of the global population, they contribute nothing to the most pressing task of improving basic health care in poor countries.

Second, arguments concerning the importance of individual consent are often met with statements to the effect that they put private interests above public interests and surely this is sometimes the case. However, there are important public interests at stake as well in maintaining the ethos of voluntary consent to participation in database research. Neglecting it may weaken a democratic society in the long run. A policy of open consent could also be detrimental to the public trust in science and thus destroy a major social asset. An open consent of this kind does not provide participants with the information necessary for them to make a meaningful choice, i.e. to act in a voluntary way on a basic understanding of the matter. It transfers the reflection on population research from the participants to regulatory institutions

(saying in effect "leave the thinking to us"). Thus, motivations for scientific literacy and awareness of the public would be reduced, something which is not in the public interest. The benefit view as I have described it thus ignores important benefits related to human agency.

In light of this it can be a misleading description of the protective position to say that it focuses on individual interests that are contrary to general social goods, unless we have a very narrow understanding of such goods. Effective regulation of genetic population research which protects people against undue risk, hinders discrimination and manipulation of individuals, is in the public interest in the long run, even though it limits the leeway of researchers. From this perspective, the sharp distinction between individual and collective interests is misleading. Providing options for participants' deliberation and preserving other conditions for human agency and reflection are not mere private interests. However, these objectives are not best served by obtaining specific informed consent from otherwise passive participants.

In the context of my discussion of the relationship of these views to democracy and citizenship, their common shortcomings and limits have become more conspicuous than their differences. While the protective position puts security of individuals above other considerations, the benefit view regards the population as a collective resource for biotechnology. It is not surprising, therefore, that a prevailing position in biopolitics is a *combination* of these two views and their major limitations. This combination takes on the following form, for example in discussion about population biobank research: In order to mine the population for maximum benefits, privacy protection needs to be extraordinarily strong. In this way, strong data security becomes one of the very preconditions of the utility view. This combination characterized the database affair in Iceland.

In this combination, the otherwise contrary positions regarding database consent disclose an important underlying and hidden presumption concerning the scientific citizenry that is being created. Positions, which place the main emphasis either on protecting the participants' private domain from illegitimate interference or on providing them with material benefits, see people primarily in a passive role. They do not provide reasons for implementing policies that facilitate actions of the citizens in the public sphere. In this way they are part of a research culture which contributes to scientific illiteracy and disregards the active elements of human agency which are crucial for the democratic citizen.

This is not surprising because these two visions of the citizen tend to complement each other in contemporary society. These visions emphasize, on the one hand, the person in the domestic private sphere where the safeguarding of freedom from illegitimate interference is of primary importance. On the other hand, the citizen is seen as a consumer and worker in the economic sphere, contributing to the economic prosperity of society, upheld largely by high standards of health in the population. In this way, both the protective and the benefit positions relate more to people as private persons, consumers, workers and patients than as democratic citizens.

However, as I have indicated, both positions harbour elements that could be developed in directions which are more conducive to a reflexive democratic culture. This is more obvious in the protective position which aims to safeguard important

conditions of human agency. By insisting on specific informed consent for participation in biobank research, opportunities can be created for people to reflect on their participation but at the cost of making biobank research practically impossible. The benefit view, on the other hand, justifies open consent by reference to the material benefits to be reaped from biobank research but at the cost of losing the important social benefits related to active human agency and deliberation. These positions need, therefore, to be complemented with emphasis on factors that can increase public awareness of population research and strengthen the conditions for their decisions and responsibility for participation in the research.

Engaging Citizens

The third view that I want to discuss draws upon ideas of the active citizen which has roots in republican ideas of citizenship and deliberative democracy (Benhabib 1996; Cohen 1997). This view does not reject the moral elements of the protective and the benefiting positions but seeks to overcome their shortcomings by taking other considerations into account. Clearly, one should not be forced to choose between either protecting individual privacy and contributing to social benefits or increasing the awareness of the citizenry about science and biotechnology. It is necessary to protect the citizens against the misuse of both private and public power in a democratic society, but this is a very limited view on the citizens' interests. The benefit view also harbours important considerations but the promised benefits can be questionable. This is especially the case when the biobank research is conducted by a private company, as in Iceland, because the mutuality of benefits that is secured in a social system of health care is absent. I am not saying that there are no public benefits to be reaped from commercial biobank research but that an appeal to them is not a sufficient justification of open consent.

Before considering the general implications it would have for biopolitics to take these elements of the active citizen more into account, I will consider its impact on the example of consent for biobank research. It is understandable that the question of consent for participation in database research has been in the limelight of discussions about genetic data collections and biobanks. Population data collections are *resources* for genetic research and it is impossible to describe in detail the research that will be performed on the data at the time of collection. This can lead to the following dilemma: *Either* data will be collected with specific informed consent which emphasizes interests of individual participants but radically diminishes the flexibility of researchers and the possible benefits of the research *or* data will be collected with open consent which maximizes research flexibility but can undermine the option for reflection and other conditions for moral agency of the participants. The challenge is to show how this dilemma can be dealt with without risking either the possible human welfare benefits or the moral agency interests at stake.

In order to avoid the pitfalls of the specific and the open consent, alternatives that are intended to strike a balance between the researchers' need for flexibility

and the ethical demand for protection of participants' interests have been proposed (Greely 1999; Caulfield et al. 2003; Árnason 2004; Kaye 2004).[1] The main thrust of these proposals, which have different emphasis, is that participants should be asked to authorize the use of their data for described health care research. They would be informed about the conditions for use of the data, such as how the research will be regulated, how they will be connected to other data, who will have access to the information and how privacy will be secured, and that they will only be used for described health care purposes. Most importantly, participants would be told that they and/or their proxies will be regularly informed about the research practice and that they can at any time withdraw from particular research projects.

Such an authorization or permission would both allow participants "to meaningfully act on their continuing interests in their health information" (Caulfield et al. 2003) and provide science ethics committees with a meaningful ground for determining further use of the information. Such further use can be restricted to comparable research where members of research ethics committees can reasonably argue that the additional research would not have affected the participants' initial decision to participate. Such a policy could maintain the motivation for participants to reflect on their participation in research and to stay informed about how their data are used and for what purposes. An authorization policy might thus contribute to informed, reflective and responsible research participation that can underpin public trust in research practices. None of these would flow from an open consent policy for database research.

These considerations are relevant for avoiding two of the most serious dangers of scientific research on humans, those of deception and coercion. The authorization proposal implies that individuals are offered "simple and realistic ways of checking that what they consent to is indeed what happens and what they do not consent to does not happen" (O'Neill 2001). If the latter happens, they can opt out. In addition to strengthening the basis for non-deception, this last point aims at securing the purpose of non-coercion, since it implies that participants need not continue research against their will (Kristinsson and Árnason 2007). In this way interests associated with moral agency and the moral purpose of informed consent may be best secured and that, in the last analysis, is crucial in any evaluation of advantages to human society.

It is integral to the authorization model that participants will be encouraged by regulatory institutions to follow the research practices. This provides conditions for an active opt-out clause which is likely to create more informed and critically aware citizens and is also conducive to *informed* trust. This position thus enables active *scientific citizenship* because it emphasizes the creation of conditions or opportunities for citizens to reflect on their participation in scientific research. Contrary to the protective policy of specific informed consent, these conditions for participants'

[1] An interesting solution of the Icelandic National Bioethics Committee is to provide a "menu" of three types of consent which the participants themselves can choose between. Most opt for the widest one, which permits use of samples for other research than covered by the initial consent, provided that the National Bioethics Committee and The Protection of Privacy institute have approved the research.

deliberation do not come at the cost of a flexible biobank research. There is no requirement of a continuous re-consent in order to meet formal procedures, but a dynamic interchange which has the primary aim of keeping participants informed and aware. Such scientific citizenship need not thwart the possibilities of reaping the benefits of biobank research; it refuses, however, to reduce participants to being merely a passive part of a resource.

The notion of scientific citizenship is used here in a normative, critical way and not only as a descriptive term, where all kinds of reactions of the citizens to the new genetics are regarded as examples of biological citizenship or "different citizenship practices" in response to "new technologies which intervene on the body" (Rose and Novas 2005). This normative use of scientific citizenship can be criticized from the liberal viewpoint of "neutrality of rationale" for scientific policies (Kristinsson 2006). However, it must be emphasized that the idea is mainly *to offer participants the chance* to be active and reflective and not to *require* that they be so. It is an important tenet of liberalism that people are not passively subjected to policies and that they are provided with the *opportunity* to exercise their status as free and responsible agents. The conditions for this must not be reduced to information initially provided when consent is obtained but need to be seen in terms of options for a dynamic interchange with participants.

Guiding Vision

The objective is to create more informed or educated citizens who do not have to rely exclusively on expert knowledge but can use it in their deliberations about research participation. This, of course, is not something that can be easily realized but it is an important *vision to guide* our attempts in shaping citizens' awareness in society where biological research and biotechnology play an increasing role. This objective obviously requires that different biopolicies need to be introduced. I will only mention here two preconditions for such a biopolitics which takes the vision of the democratic citizen seriously: improved scientific education, preparing people for active participation in a society, and increased public deliberation about biopolitical matters.

Visions of the citizen are important in school curricula and education which increases scientific literacy that may contribute to more biopolitical awareness and thus create preconditions for policies which facilitate more public engagement. This effort must be aimed at the citizenry at large, at the "maxi public", so to speak, not only the "mini public" which is created in particular deliberative events. Such exercises in deliberative democracy can obviously be valuable but they need to build upon a comprehensive deliberative education of the citizens about biopolitical matters.[2]

[2] For examples of particular deliberative events, see the homepage of The W. Maurice Young Centre for Applied Ethics, University of British Columbia: http://ethics.ubc.ca/index.php?p=misc&id=5. For material aimed to educate the young in biopolitical matters, see for example the Danish

Another precondition for more democratic biopolitics is strengthened professional media and science reporting which provides the citizens with reliable information, critical analysis and creative scenarios about the socio-political implications of biotechnology. This calls for professional science journalists with insight into scientific discourse and ability to present it to the public. Improved scientific education and media can jointly facilitate informed public deliberation about biopolitical matters. This, however, will not do unless forums for public dialogue are created in society and the spaces of action and reflection open to citizens are expanded. This requires, in fact, that bioethics is not sharply distinguished from biopolitics (Hoeyer and Tutton 2005; Árnason and Hjörleifsson 2008).

The idea is clear although the task is certainly not easy. One thing to avoid, for example, is that public consultation be designed mainly as strategic means to ensure more public acceptance and institutional trust. This could result mainly in more docile public, more willingness to abide by the biopolicies that are shaped by the authorities. It is an important objective to increase trustworthiness of public policies but it is not the objective of democratic policies to construct citizens who are "vehicles" of a comprehensive biopower and "mechanisms of domination" over which they have no control (Foucault 1980). From this cynical angle it may not matter much how biopolicies are formed because the choice is merely between a vertical or horizontal exercise of power.

The Foucauldian perspective is of great heuristic value in the analysis of biopolitics but it provides limited guidance for the task of framing more constructive democratic biopolicies. As part of that task, it is necessary to create opportunities for citizens to develop their thinking and increase their understanding of science and impact on biopolicies. This vision implies a belief in the intrinsic value of consultation and public dialogue, more in the spirit of democratic deliberation. However, isolated deliberative events can be used simply to solicit citizens' values or preferences without engaging them in critical deliberation which requires that the participants adopt a civic standpoint.

Although the guiding vision is important, we need to, as Alan Irwin suggests, "move beyond general exhortation alone over such matters and instead explore the social processes, underlying assumptions and operational principles through which scientific citizenship is constructed in particular settings" (Irwin 2001: 15). It is important to move the discussion of public participation "from the level of sloganizing to an important focus for both social scientific and practical investigation and experimentation" (Irwin 2001: 16). Among the complexities involved in the shaping of more democratic biopolicies are questions like the following: What information is provided and how it is provided to the public? How are issues to be framed for public debate? How is public consultation to be institutionally located? No doubt, there will be a constant tension between science, politics and the public will, and this tension will take on various forms which depend on the subject matter. The

Ethics Council: www.etikoglivet.dk/sw11738.asp. Similar educational projects for the young are sponsored by the Norwegian Biotechnology Advisory Board and the Swedish National Council on Medical Ethics.

challenge is to transform this tension into a creative power for innovative policy making.

It is in the nature of creative democratic politics that it is in constant search for more efficient channels for people to be informed about decision-making and to increase their impact on policy making (Arblaster 1987). There is no universal solution to how this is to be done. The important thing is the willingness and effort to look for the appropriate approach in each case. In this chapter I have argued that one way to approach this task is by a policy of a dynamic authorization for the conditions of use of data in population databank research. It is clear, however, that much more thinking is needed in the context of research biobanking if we find it at all important to have a vision of an educated and engaged citizen. The exercise in deliberative democracy in relation to biobank research is now in its starting phase and there are interesting times ahead. It is of crucial importance that deliberative democracy is not used to facilitate the benefit view by making the "mini public" more accepting of the current practices and thus seeking to acquire a premature democratic legitimization.

A democratic legitimization in the spirit of deliberative democracy can only be reached by a preceding critical discussion in the public sphere, the outcome of which is translated into political will formation. As Joshua Cohen writes in the spirit of Habermas, "free deliberation among equals is the basis of legitimacy" (Cohen 1997: 72). This should not be understood as a realistic aim as much as a *critical idea* which can help identify the role of power, coercion and ignorance in social decision-making. This critical idea can be used for example to distinguish claims based on narrow self-interests from those conducive to the general public interests. This critical idea of freedom in public deliberation needs to be taken more into account in the exercise of deliberative democracy if it is to contribute to overcoming the limits of the protecting and the benefit positions with respect to research biobanking and create conditions for more informed and engaged citizens.[3]

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[3] Thanks to the editors for helpful comments on this chapter.

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