Biobank governance in the post-genomic age

Biobank governance is about the regulation of the relationship between individual citizens, society and biobanks. Its key agenda is to link society, citizens and biobanks with respect to issues of consent, privacy, ownership, access and benefit sharing. With the transformation of biobank research from local/national activities towards transnational projects and the emergence of post-genomic medical research, biobanks need to establish novel governance structures. We consider governance solutions that focus on ‘bioethical–theoretical’ arguments to be of only limited value in this context. By contrast, we think the key lies in developing participatory arrangements that are responsive to the views of patients and ‘lay people’, and also operate on a transnational level. The social–political and communicative competence of biobank infrastructures must be improved, thereby assuring the long-term legitimacy and commitment to these often highly expensive projects from a large variety of different stakeholders over the decades.

Biobanks as topic of governance
In recent years, biobanks across the globe have received much attention as a new key infrastructure and resource for biomedical research and drug development. However, the task of either transforming existing biospecimen collections into a new genomics research tool or of creating new population-based collections for research purposes is not only a scientific–technical challenge, but also a challenge for governance [1].

So far, the governance of biobanks, in particular of population-based genetic databases, has caused attention through instances of controversy and resistance, for example, in Iceland. The increased public–political attention to human genome research and to the collection of biological materials has also heightened pressure on biobanks, which had received little public attention in the past – such as biobanks in the field of tissue collection – to reconsider their means of interaction with society, and thus regulatory practices and strategies.

Legally and technically, biobank governance today has remained a heterogeneous patchwork operating through mostly local or national guidelines, codes of good practice and ethics regulations. Although the general governance issues to deal with turned out to be quite similar for most countries, differences on the scientific–technical level of biobanks are worked out on the governance level in different ways in different contexts. However, in the post-genomic area, biobanks are facing new types of governance challenges. There is a need for new strategies to regulate the relationships between individual citizens, society and biobanks, and to find new solutions for dealing with the core issues of consent, privacy, ownership, access and benefit sharing in the linking of society, citizens and biobanks.

Biobanks and biobank-supported research are no longer localized endeavours and they typically transcend the ‘classical’ doctor/researcher–patient relationship. Increasingly, biobanks are becoming networked and international projects in the context of post-genomic medical research. In this situation, they are facing an increasing pressure to establish novel governance structures, linking them to a variety of social, legal and political contexts that are local and global at the same time. Since it cannot be taken for granted that technical and ethical solutions that satisfy local biobank needs for governance in one place also work in others, we propose to dedicate more attention to develop a set of mechanisms that allow for a better negotiation between biobanks and society. We consider ‘bioethical–theoretical’ solutions to be of limited value in this context. By contrast, participatory arrangements that are responsive to the views of patients and ‘lay people’, and also operate on a transnational level, will be key to such novel arrangements [2]. What needs to be accomplished is to increase the social–political and communicative competence of biobank infrastructures, thereby assuring long-term legitimacy and

KEYWORDS: benefit-sharing • biobanks • governance • participation • privacy

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commitment to these expensive projects from a large variety of different stakeholders over the decades.

**Human bodies, citizens & biobanks**

Biobanks cannot exist or function without establishing relations with human bodies. They study participants in cohort studies and patients donating blood or tissue, and they connect with citizens and society. Thus, the challenge of biobank governance is to establish and stabilize the myriad relationships among tissue samples, patient records, blood, DNA and tissue-donating patients, participants in biobank studies, notions of citizenship and human rights, and general understandings of research and medical ethics.

The interrelated topics of informed consent, privacy, autonomy and confidentiality feature prominently in this discourse and are the core concerns of biobank governance. Historically, at the center of this endeavor is the concept of protecting the autonomy of the patient or research participant as an individual and as a citizen, armed with political rights and equipped with the capacity to make informed, rational decisions. Inherent in this idea is that individuals have the right to decide if their body, body parts and associated data are to be used, and consent for such use must be obtained before any parts or data associated with a particular human body are actually used [3, 4].

At first glance, the idea of informed consent seems relatively straightforward. It is based on the idea of individual autonomy, which is an ideal of modern culture – the image of the free individual making informed decisions based on personal will and preferences. In the literature, consent procedures are seen on a continuum from highly specific consent to blanket consent. For biobank research, this could mean one of three things:

- An individual consents to a specific study to be conducted with his or her tissue, DNA and data;
- The individual consents to research on a specific disease;
- The individual gives general consent, that is, for biomedical research permitting the use of the sample for any purpose [5, 6].

Furthermore, consent is not something that is given once and then cannot be reconsidered or rescinded. The Declaration of Helsinki, today’s authoritative statement on biomedical ethics, states that consent of research subjects can be withdrawn at any time without reprisal [7]. However, the post-genomic context issue of informed consent is more complicated than it looks at first glance.

**Towards the new governance of consent & privacy in biobank research?**

The collection and storage of such large quantities of potentially sensitive data is not an ethical governance issue in itself. For decades, government agencies have collected and stored data for purposes of medical and social wellbeing of the populations they governed.

However, biobank infrastructures today differ from these ‘older’ state practices in at least two interconnected ways that potentially affect their legitimate operation in the long term. First, transnational biobank networks obviously transcend the national realm in which established democratic and legitimate decision-making procedures are available. Actions of traditional national bureaucracies are deemed to be legitimate, because in theory, they are directly based on and accountable to the national sovereign, which is embodied by national parliaments and their governments. Second, biobanks and biobank networks are not governed in a typical hierarchical command and control structure. Their governance frameworks are examples of modern policy networks that consist of actors with different but mutually dependent interests. Although such policies are densely embedded into larger macro-political and -economic structures [8], they conflict with stereotypical notions of a clear-cut distinction between state and social actors and the idea of the state as a superior center of social control [9, 10].

The example of the Icelandic Health Sector Database illustrates this fact nicely. Although the Icelandic Althing (the Icelandic parliament) voted clearly in favor of the plan, opposing voices that emphasized problems of privacy and the protection of medical information were able to question the legitimacy of the whole project. Already in 2003, more than 20,000 Icelanders had decided to ‘opt out’ from the database project [11]. The opposing voices managed to increase the financial, administrative and political transaction costs significantly. According to Palsson, the Professor of Anthropology at the University of Iceland (Reykjavík, Iceland), they even managed to increase the technical transaction costs of the project since complaints of the biobank’s staff suggested “that the targets set for protecting the anonymity of samples and data were both too high and too cumbersome to work with” [11].
Questions of how to obtain informed consent have been a key issue in the biobank debate in Iceland and elsewhere during the late 1990s and early 2000s. In the years afterward, towards 2010, the topics of genetic privacy and confidentiality, both closely linked to informed consent, gained importance in the discussion. Genetic privacy is typically framed as informational self-determination that is threatened by the involuntary disclosure of genetic information [12]. For some time, privacy issues have been discussed as being potentially problematic for biobank projects since they collect and store large quantities of potentially sensitive data [13–19].

Privacy and confidentiality became key issues in the creation and utilization of biobank infrastructures from a legal point of view. Not at least because there still exists a considerable degree of variability and uncertainty in the meaning of legal and technical terms such as (non-)anonymous, identified and identifiable [16]. Helgesson and Johnson emphasize that according to the declaration of Helsinki, research subjects are not supposed to have any interests in the biological samples, other than those they have in relation to their personal data [20]. However, protecting this interest therefore becomes a critically important task, since the declaration states that [7]:

“Every precaution should be taken to respect the privacy of the subject and the confidentiality of the patient’s information.”

Elger and Caplan state that in general, research using identifiable samples creates an obligation to obtain informed consent and approval of the protocol from a research ethics commission [16]. In addition, the United Nations Educational, Scientific, and Cultural Organization (UNESCO) International Declaration on Human Genetic Data, adopted in October 2003, makes it clear that consent to store and use biological samples that are collected for medical or scientific research purposes may be withdrawn, unless the samples are “irretrievably unlinked to an identifiable person” [21]. According to Elger and Caplan, this obligation would create a considerable challenge for most biobanking projects because samples that contain any trace of DNA are hardly nonidentifiable. Samples are considered to be identifiable if the information that allows for identification – name, address and so on – is associated directly with the tissue. The term ‘anonymized’ means that biological material is stored alongside associated information, such as type of tumor, medical treatment and donor’s age, but all the information that would allow for the identification of the research participant or patient is stripped either irreversibly (unlinked anonymized) or reversibly (linked anonymized) [16].

However, their view is challenged by several authors and isn’t in line with the nomenclature that was authorized by the European Medicine Agency in 2007. Nietfield challenges their view that samples which contain any amount of DNA aren’t truly anonymous because it is possible to identify donors through DNA fingerprinting [22]. He raises the point that the term ‘identified’ in general is:

“…accepted to compromise a name, as well as data of birth, but DNA fingerprinting can only determine with a certain probability that a biological sample originates from a specific individual.”

However, this doesn’t automatically lead to a status of identification because DNA doesn’t contain personal identifiers in itself [22]. Hansson has pointed out that in order to evade such terminological difficulties, the European Medicine Agency has suggested a nomenclature that fits the needs of current research practices and their ambitious goals for harmonization [23]. According to this nomenclature, ‘identified data and samples’ are labeled with personal identifiers, such as names or identification numbers, and are therefore directly traceable back to the subject. Such ‘identified data and samples’ can be ‘coded’ (single or double coded) so they do not directly carry any personal identifiers any longer. Initially, ‘coded’ data can be anonymized if the link between the subject’s identifiers and the code is subsequently deleted. Then again ‘anonymous data’ and samples are never labeled with personal identifiers when originally collected.

Although these definitions help to deal with a couple of legal problems and uncertainties, they do not necessarily protect biobank projects from running into political difficulties during their development and operation phase. Even if, from a legal point of view, it might be sufficient to ‘code’ samples and data in order to store them in biobanks and retrieve them for research purposes that are not specified at the time of the donation, this does not mean that biobank projects won’t be confronted with political opposition from certain groups of citizens or patients that feel that their individual or common interests in privacy are not sufficiently taken into account by these projects.
For these reasons, privacy-enhancing technologies that provide coding techniques to anonymize donors whose samples and data are stored in biobanks have recently become more important [24]. However, according to Malin, who analyzed privacy-enhancing technologies in order to assure the impossibility of reidentification, none of the analyzed systems was impregnable to reidentification [25]:

“There exist patterns of flaws due to neglect of inferences that can be made from genomic data itself and the environments in which data are shared.”

Moreover, it is crucial to bear in mind that all strategies to deidentify (genomic) data by transformation of attributable value are accompanied by a loss of information [17]. Although bioinformaticians are still improving their attempts to k-anonymize [26,27] and l-diversify [28] datasets (‘k’ and ‘l’ are placeholders, specifying the minimal, necessary number of data twins, which prevent sensitive data from being directly linkable to individuals, to be created by the system), some basic tensions are inescapable despite the introduction of ever more sophisticated technical fixes. It is at least not feasible – if not entirely impossible – to sever all the links between potentially identifiable data, because it is exactly these sort of links that enable biobank research to uncover the complex, hidden factors that influence health or disease outcomes. Biobank projects that aim to facilitate the scientific understanding of common complex, multifactorial diseases, which are caused by a large number of small additive effects [29], are in one way or another dependent on the fact that banked material and information remain linked in ways that potentially identify donors in the future.

Public good & the governance of biobanks

Lunshof and colleagues, in their reasoning regarding the governance of biobanks, see established concepts of research ethics ‘stretched to their limits’ by the flood of information created by recent advances in high-throughput genomic technologies, the increasing number of genome-wide association studies and the publication of ever more comprehensive individual genome–phenome datasets [19].

They conclude that the promises of strict ‘ informational privacy’ and confidentiality can no longer be upheld because, despite a great deal of effort to improve data safety, there are still ways to work around the available anonymization and deidentification systems. Moreover, current developments increasingly question the idea of confidentiality of data itself because it relies on the assumption of stable binary relationships between patients and physicians. However, the domain of (post-)genomic research increasingly transcends this bilateral and personal trust relationship between these two groups. This relationship has increasingly become superseded and replaced by multilateral and impersonal governance structures, and social relations that are indispensable for the operation of biobank projects. Today, the global sharing of samples and data is actively pursued by a number of international projects, including the Public Population Project in Genomics and the Biobanking and Biomolecular Resource Research Infrastructure.

Since absolute data safety is an illusion and the sharing of samples and data has become a standard practice in the life sciences and especially in genomics, Lunshof and colleagues endeavored to redesign the informed-consent procedure in ways that would be suitable for the reality of biobank research in the post-genomic age. They suggest what they call ‘open consent’. The open-consent model refrains from promises of anonymity, privacy or confidentiality and instead, replaces autonomy as the leading moral principle with veracity. The model emphasizes the importance of providing accurate and transparent information to donors, in order to give them the possibility to make an informed judgment about what kind of risks their participation might incur [19].

The argument of Lunshof and colleagues is based on ideas from communitarian ethics, which has become increasingly important in the ethical debate on biomedical issues. This school of thought relies on concepts such as mutuality, reciprocity, solidarity and citizenship [30], and dismisses what Lunshof and colleagues refer to as ‘old ethics’ grounded in autonomy, with its focus on individual rights, because the latter are not applicable to current practices in the life sciences [18]. Proponents of what has been called the ‘communitarian turn in ethics’ rightly emphasize that individuals should not only be understood and portrayed as acting in ways that maximize their immediate personal interest, but rather as altruistic individuals who are concerned about the communal aspects of their actions and decisions and the promotion of the common good – which is typically presented as ‘the progress of science’ or ‘population health’.

However, in our view this approach still relies on quite an abstract or general notion of the ‘individual’, the ‘citizen’ or the ‘data subject’
who should be adequately protected and whose interests or motivations (even if they might be altruistic) should be taken into account. As we have tried to show, the conflict between individual privacy and interest, on the one hand, and the public good, on the other, is more a topic of philosophical insinuation rather than a real world problem for the interaction between society and biobanks. Although we certainly agree that privacy is a value for individuals to enjoy, we emphasize Bennett’s and Raab’s point that it would be relevant to find out “who gets what protection of privacy and why?” [31]. In addition, we think it is worth considering what the term ‘privacy’ means to different people in different (social, political or economic) contexts. Arguments that frame the issue only on the basis of a dichotomy of private rights versus public goods obscure the complexity at hand. Delineating a boundary between what is deemed private and what is treated as public is no straightforward intellectual, technical or administrative task [32]. From its very beginning, political modernity has been shaped by struggles over the relationship between private and public domains [33]. Since these controversies are therefore essentially political, we cannot assume that the meaning of the word ‘privacy’ is straightforward, homogenous and stable in the context of biobank infrastructures. This is especially important as we see the operation of biobank governance as a policy network, which (by definition) cuts across clear-cut distinctions between a public realm that is managed by the state and a private sphere that remains outside of its institutions.

Conceptual apparatuses that offer undifferentiated categories like ‘patients’, ‘donors’, ‘citizens’ or ‘data subjects’ divert attention from the fact that certain levels of privacy may be unevenly distributed within but also between societies according to key social categories, such as gender, age, race, class and others. Privacy might have a different meaning for a farmer in rural China donating his blood to a European-run biobank project compared with a donor in The Netherlands giving his blood to a cohort study operated by a nearby hospital. Viewing this donation as a contribution to the public good has an entirely different meaning in the case of the Chinese farmer, who neither has much access to a healthcare system nor lives in Europe, as opposed to the Dutch participant, who enjoys full social insurance and thus is well positioned to fully profit from most advances in Dutch medical research. Like Bennett and Raab, we think it is reasonable to suppose that – similar to other social values – such inequalities in the distribution of privacy do exist. Discussions regarding the (potentially) uneven distribution, of future benefits of research conducted with the help of biobanks, across societies, has gained some attention, as will be discussed below when we address the issue of benefit sharing. However, we diagnose a remarkable silence on the issues of possible (re-)distributive effects of levels of privacy, which might occur right now during the creation phase of many biobank projects.

**Governing ownership & benefit sharing in biobanks**

Although the private industry has played a role in recent biobank business models, the Icelandic case demonstrates the difficulties of such forms of support for biobank research networks that do not necessarily yield quick economic returns, yet are based on blood, tissue and DNA, which quickly raise difficult questions of ownership and benefit sharing. In the UK, the developers of UK Biobank (Cheshire, UK) had determined that they would support a position in which the biobank could be accessed by commercial entities, but this access would be subject to strict ethical protocols. Furthermore, the biobank project would be a public venture funded by UK medical charities and government departments.

As a result of the complex issues, governments have stepped in largely as funders of biobank projects, which does not necessarily simplify issues of access and patenting. In this context, the concept of benefit sharing has been gaining prominence in the recent debate regarding biobank governance and as a strategy to deal with the public nature of most biobank projects. According to the Human Genome Organization (HUGO) ethics committee [34]:

“A benefit is a good that contributes to the wellbeing of an individual and/or a given community (e.g., by region, tribe, disease group).

Benefits transcend avoidance of harm (nonmaleficence) in so far as they promote the welfare of an individual and/or a community.

Thus, a benefit is not identical with profit in the monetary or economic sense. Determining a benefit depends on needs, values, priorities and cultural expectations”.

However, a weakness of the concept of benefit sharing in the context of biobanks is that actual health or monetary benefits created by biobank projects will occur only in the (distant) future (if at all) and are not measurable in an exact way. Therefore, it is difficult to foresee how such
(positive) externalities should be distributed. Even if health benefits in the form of health information become available in the context of biobank research for participant/donors, it is far from clear if and to which extent they should be made accessible to these participants in biobank projects, as the example of UK Biobank shows [35]. It must be taken into account that biobank projects are currently largely funded with public money. Therefore, compensating the public at large would be equivalent to returning taxpayers’ money to taxpayers. Sharing accruing benefits only with participants or donors would mean setting financial incentives for participating in research. On the one hand, most commentators don’t judge financial incentives to be desirable as far as ethical or moral considerations are concerned [36,37] and, on the other hand, they interfere with ideas of an accurate scientific research design because it could lead to overrepresentation of groups that are financially more dependent on financial incentives than other groups.

Since the idea of ‘benefit-sharing regimes’ seems to serve as appealing rhetoric in relation to biobank projects and ‘ethical governance’, but actually has little merit when it should be applied in ‘real world’ biobank governance, Winikoff and colleagues have proposed the participatory model of the biotrust [38–40]. The model goes beyond recent discussions regarding benefit sharing that exclude research participants from governing the resources they help to create. Hence, he suggests a model of ‘partnership governance’ and thus a shift from ‘benefit sharing’, and its emphasis of distributive value, to a mode of ‘power sharing’, which is essentially a procedural one, in which donors in biomedical research can become active participants with the ability to shape the concrete meanings of the terms ‘public good’ and ‘privacy’. Building on a foundation of traditional informed consent and expert ethical review, this model attempts to introduce the governance model of a ‘donor-advised trust’ in which “the materials are actually co-managed by donors, trustees and the sitting ethics board in accordance to the charitable intent of the donors” [40]. Since the issues for biobank governance we discussed above are, in our view, essentially political and not only technical, we think that ideas like this are interesting to experiment with in practice. This is needed because what is referred to by the distinction between ‘public’ or ‘private’, the term ‘ownership’ and especially by the term ‘good’ are issues that are definitively outside of the domain of expert decision making and need more participatory arenas to arrive at legitimate political decisions, which are made in policy networks that govern contemporary biobanks and operate (at least partly) outside traditional state institutions, such as parliaments and bureaucracies.

### Conclusion: towards new participatory modes of biobank governance?

In this report, we have discussed the significant challenges for post-genomic biobank governance when attempting to regulate the relationship between individual citizens and society in the biobanking process. With the transformation of biobanks into large-scale infrastructures of post-genomic research, neither traditional concepts of biobank governance from bioethics nor ‘classical’ models of sharing the benefit of these projects within society seem to work properly.

What would be the best way out of this dilemma for biobank governance? In the recent debate on biobank governance, there was a tendency to develop more open, exploratory and participatory modes of governing biobanks as an essential precondition of their operation. In these settings, levels of privacy and scientific knowledge must both be acknowledged as social values.

Accordingly, decision makers will have to consider developing modes of inquiry and reflexive models of ‘lay participation’ with diverse groups, and a new ‘empirical’ communicative ethics, possibly also Web 2.0 based, in order to develop sensibility for what the public interest might be in issues such as privacy or benefit sharing. Given that the individual and social meanings of terms like ‘privacy’ and ‘genetic information’ are by no means fixed, it is relevant to take into account the perceptions of the lay public. Trust can be generated neither by technical solutions nor by increased transparency alone. To increase the level of data security doesn’t necessarily enhance the quality of a trust relationship. Likewise, benefit sharing is not easily implemented if it is to constitute more than a rhetorical strategy and potentially stretches from biotrust models to providing health information for participants in biobank cohort studies. The way these procedural questions will be negotiated and dealt with in the future will be crucial for the success or failure of biobanks.

As important as ethical, practical administrative and information technology-based efforts are to link society with biobanks, today the reality of developments in large-scale biobanking and genomics has created a highly challenging constellation for biobank governance in which the solutions are not entirely clear. Newly developed technologies, such as high-throughput low-cost
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sequencing, are applied increasingly to human genome and phenome datasets. Comprehensive datasets establish informatics links among genome sequences and extensive phenotype analysis, thereby potentially enabling the identification of individuals whose DNA sequence they contain. With the intention of increasing the range and quantity of data, large-scale research platforms are being built that assemble, organize and store data and biospecimens, and then distribute them to researchers. Thus, new data flows, genome-wide analysis and novel arrangements among data, patients and researchers are being established [17]. Large-scale biobanks are often longitudinal and require extensive exchange of data and specimens, implying that a particular sample might be used for varying purposes over the years. This implies that there is considerable pressure for biobanks to deal with issues of concern regarding data security and privacy in the face of the existence of the limits to give comprehensive guarantees that these issues can be satisfactorily dealt with technically. To us, the strategy to face up to this challenge for biobank governance by bioethical argumentation alone and diffuse reference to the public good does not seem to be very promising. Creating a new governance infrastructure to deal with individual and collective desires to be informed of and also

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<td>* In the post-genomic age, biobanks are under pressure to establish novel governance structures that mediate and guide in a variety of social, legal and political contexts.</td>
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**Towards the new governance of consent & privacy in biobank research?**

* Biobank governance is a heterogeneous patchwork operating through mostly local or national guidelines, codes of good practice, formal and informal standards, and ethics regulations.  
* In the post-genomic area, biobanks are facing new types of governance challenges. Privacy, consent, confidentiality and benefit sharing remain the key issues in today's governance of biobank infrastructures. However, there is a need to develop new strategies to address them.  

**Public good & the governance of biobanks**

* With the transformation of biobank research from a localized endeavor that typically does not transcend the 'classical' doctor/researcher–patient relationship to networked, internationalized projects in the context of post-genomic medical research, biobanks are facing serious difficulties to guarantee privacy and anonymity in the research context. In addition, the fair distribution of benefits from biobank research has become a prominent topic.  
Since absolute data safety is an illusion and the sharing of sample and data has become a standard practice in the life sciences and especially in genomics, some bioethicists subscribing to the so-called 'communitarian turn in ethics' have suggested to redesign the informed consent procedure in ways that would be suitable for the reality of biobank research in the post-genomic age.  
* These bioethicists argue for adopting an open-consent model that refrains from promises of anonymity, privacy, or confidentiality in biomedical research, and mainly invites us to face up to the realities of contemporary post-genomics research with its limits to be able to fully guarantee privacy and confidentiality to research participants and patients.  

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* The ‘communitarian’ ethicists emphasize that individuals should not only be understood and portrayed as acting in ways that maximize their immediate personal interest but rather as altruistic individuals who are concerned about the communal aspects of their actions and decisions, and the promotion of the common good – which is typically presented as ‘the progress of science’ or ‘population health’.  
* However, such generalized approaches towards core ethical issues such as consent and privacy are highly problematic. Certain levels of privacy may be unevenly distributed within, but also between, societies according to key social categories such as gender, age, race, class and others.  
* Privacy might have a different meaning for a farmer in rural China donating his blood to a European-run biobank project as compared with a donor in the Netherlands giving his blood to a cohort study operated by a nearby hospital. Viewing this donation as a contribution to the public good has an entirely different meaning in the case of the Chinese farmer, who neither has much access to a healthcare system nor lives in Europe, as opposed to the Dutch participant, who enjoys full social insurance and thus is well positioned to fully profit from most advances in Dutch medical research.  
* Hence, just like in the distribution of benefits, inequalities also exist in the distribution of privacy and confidentiality. These facts need to be integrated into novel approaches towards biobank governance.  

**Conclusion**

* In this report, we point to the challenges of biobank governance in the post-genomic age, and to limits to the theoretical–bioethical approach towards biobank governance.  
* We suggest considering new strategies of participatory governance in the biobank field. In such participatory arrangements, experts share their decision-making power with donors and lay people who are no longer construed as abstract ‘would be’ beneficiaries of research. Instead, they become engaged in shaping jointly concrete meanings of the terms ‘privacy’ and the ‘public good’.  
* Trust and legitimacy can neither be generated by technical solutions nor by increased transparency alone.  
* The way procedural decision-making questions are negotiated and dealt with in the future will be crucial for the success or failure of biobanks.
gain access to possible existing results in biobank research seems to be in a much better proposition to deal with current and future challenges for biobank governance.

**Future perspective**

We expect that biobanks will significantly gain importance as a key global infrastructure and tool in biomedical research. As a result, public attention and interest in biobanks will increase considerably over the next decade. While today most people either have no or only scant knowledge of biobanks, this will change in the future. Therefore, biobanks will become a much discussed, possibly also a hotly contested topic. Hence, it will be essential to have persuasive models for the interaction of biobanks and the public in place. Failure to do so might result in the failure of biobank projects.

‘Classical’ modes of biobank governance, such as by law, ethics committees and recommendation, or citizen juries, will turn out to be insufficient. The more biobank research will be identified as a cornerstone in developing personalized medicine, the more a broad variety of stakeholders and public will emerge around biobanks. Accordingly, decision makers will develop new modes of inquiry (such as panel-based focus group studies) and reflexive models of ‘lay participation’ with diverse groups, based on new ‘empirical’ communicative ethics, possibly also Web 2.0 based, in order to develop sensibility for what the public’s interests and concerns might be in issues such as consent, privacy or benefit sharing in biobanking.

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No writing assistance was utilized in the production of this manuscript.

**Bibliography**

Papers of special note have been highlighted as:

* of interest
** of considerable interest

2 ** Systematically develops the notion of biobank governance and brings together authors from a variety of disciplinary backgrounds to present and discuss governance problems of key biobanks in Europe, the USA, Australia and Japan.
** Gives an important introduction to the problems of genetic privacy from the viewpoint of communitarian ethics.
* Gives a valuable discussion on the European Medicines Agency’s nomenclature regarding coding.
* Key publication that gives an important sketch on the viewpoint that is introduced by the communitarian turn in ethics.
** Required reading for those who are seriously concerned about the politics of privacy.
* Gives an overview of the author’s proposal of the donor-advised trust. It justifies its major assumptions and tackles some issues raised by some earlier critical comments.