Biobank governance: heterogeneous modes of ordering and democratization

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Received: 5 July 2011 / Accepted: 17 October 2011 / Published online: 7 December 2011
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Abstract The great interest in biobanks, the related, substantial investments, and the expectations connected with them raises the question of how to explain the relative successes and failures of contemporary biobank projects. In this article we will present and discuss areas that need ongoing attention by many stakeholders in order stabilize and utilize biobanks and biobank networks in the future. Our aim is to present and utilize an analytical model for comparing structures of biobank governance. The governance model we deduce from empirical case studies is not a well-ordered, almost bureaucratic type of government. The patchwork character and the interrelatedness of heterogeneous activities that constitute biobank governance in its multiple dimensions will be highlighted. Biobank governance should therefore be understood as strategy for patterning a network of interaction that unfolds within and across a number of different fields including a variety of activities that go beyond regulatory activities: the scientific/technological field, the medical/health field, the industrial-economic field, the legal-ethical, and the sociopolitical field. Our account emphasizes that biobanks are not technical visions that operate vis-à-vis an external society. The article discusses attempts to develop participatory governance structures. It concludes that facilitating and managing the integration of a network of more or less interrelated actors, in many nonhierarchical ways, should not be equated with democratization per se, but can neverthe-

less be regarded as an important step towards a more pluralistic and inclusive style of policy making.

Keywords Biobank · Governance · Public participation · Knowledge-based economy · Technosocial politics

Introduction

The promised prospects of the so-called genomic revolution and the quest for a more personalized medicine led to a growing appetite or demand for different types of biological materials and associated clinical and lifestyle information that can be utilized for different biomedical research purposes. Today there is a clear realization in the life science community that the creation of worldwide biobanks networks and cooperation will constitute a crucial step in rebuilding the genomics/postgenomics apparatus of modern biotechnology (Cambon-Thomsen et al. 2003). In recent years biobanks have therefore received much attention as a new key infrastructure and resource for biomedical research and drug development. In a certain sense, the knowledge-based bioeconomy (Potocnik 2005) of the twenty-first century seems to be increasingly dependent on a constant supply of materials from which different kinds of bioinformation can be revealed. The task either of transforming existing biospecimen collections into a new genomics research tool or of creating new population-based collections is as daunting as it is challenging. The goal of maintaining or creating a biobank typically goes beyond the mere activity of collecting, but aims at creating value through biobanking by creating a specific knowledge value, a value for fostering health, or a specific economic value (Tupasela 2006; Waldby and Mitchell 2006). During the last decade, a variety of actors—including academic researchers, national govern-

Special Issue: *Genetics and Democracy*

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ments, international organizations like the WHO and OECD, the European Union, pharmaceutical industry, biotech companies, nongovernmental science funding organizations, and patient activist groups—have been actively engaged in creating large biobanks that collect biological material and health data from donors. But, as many examples from recent biobank development demonstrate, biobanks are neither quickly established nor easily maintained or brought to the status of an integral and useful element of modern biomedical research and development. Biobanks consist of highly complex and multiconnected networks whose smooth interrelated operation depends on a multitude of factors. Thus, the great interest in biobanks, the related, substantial investments, and the expectations connected with them raises the question of how to explain the relative successes and failures of contemporary biobank projects. This is, of course, a tricky question to answer. But if the purpose of a biobank is to create knowledge-based value, health, or economic value, or a combination of all of these, successful biobank governance means maintaining an operating network that actively pursues these long-term goals. In this article we will present and discuss areas that need ongoing attention by many stakeholders in order stabilize and utilize biobanks and biobank networks in the future. The governance model we deduce from a series of empirical case studies is not a well-ordered, almost bureaucratic type of government. Rather the aim of this article is to highlight the patchwork character and the interrelatedness of diverse activities that constitute biobank governance in its multiple dimensions. Additionally we will argue that the manufacture and employment of certain participatory mechanisms that reach beyond the typical expert communities seems to be an important element in this endeavor.

At first glance, biobanks have few areas that are at risk of failure. Collecting disease tissue samples or DNA does not seem to be an activity likely to encounter huge problems or difficulties. But this impression does not stand up under closer investigation. We suggest that biobank governance consists of a multiplicity of ordering processes that overlap to a significant degree but nevertheless operate in different domains. In fact, much can go wrong in setting up a biobank, in the collection of biospecimens and DNA, in the analysis of these samples and their storage, in the financing of a biobank, and in its relationship with different instantiations of “publics” that potentially raise a variety of unforeseeable and nontechnical and value-loaded issues. Problems can occur in all of these areas, and it is a complicated task to manage them simultaneously. In addition, complexity is introduced in this process since the domains of science and technology, healthcare, economy, law as much as the domain of public administration each operate according to different logics and emphasize different values or motives to different degrees. Conse-

quently, these domains produce value conflicts that cannot be easily solved through top-down processes of rational policy planning. Nevertheless, during the last decade, we were able to observe different efforts to create biobanks (Gottweis and Petersen 2008). A large variety of biobank governance strategies have developed under different circumstances, and we think it is possible to identify a series of difficulties that can substantially influence the value of a biobank project. In this article we will present and utilize an analytic model for comparing structures of biobank governance. We will briefly introduce this model in “[Understanding biobank governance](#).” In “[Governing scientific and technical harmonization and the assembling of a scientific community](#),” we will present difficulties that can be described as difficulties of scientific or technical ordering. “[Biobanks networks extend into fields of medicine and health care](#)” highlights different approaches to connect biobank strategies with the field of health care. In “[Biobanks and models for financing research infrastructures](#),” we discuss the delicate topic of developing connections between biobanks and the world of finance and economy. “[Ethics in biobank governance: connecting and separating biobanks from its body constituency](#)” addresses to one of the core questions for every biobank project: “How can body parts, patients, and citizens be assembled into a biomedical research process?” We will briefly review the current trends in ethical frameworks that have addressed this question from legal and philosophical points of view. But it is not possible to predict if these ethical frameworks to connect biobanks to individuals and their bodies will be accepted in the future. Therefore, in “[Biobanking and the politics of democratization through public engagement](#),” we discuss issues of sociocultural acceptance of biobanks and present practical examples of democratizing biobanking by linking biobanks with different social groups and the wider public perceptions.

Understanding biobank governance

In different policy areas, like sustainability governance (Dingwerth and Pattberg 2009) and climate governance (Bäckstrand 2008), the emergence of “new” modes of (transnational) network governance have been diagnosed and analyzed in recent decades. But how can we make sense of the concept of governance in relation to biobanks and how can it help to guide empirical investigations in this policy area?

On the most basic level, governance means the management of interdependencies. The concept signifies a shift from a centralized decision making and implementation process (government) towards a more dispersed mode of collective ordering, in which process participants agree on

collaborating for the purpose of a (set of) common aim(s) (Mayntz 1993; Nowotny and Testa 2011). On the one hand, this does not mean that governing activities by political institutions and public administrations are not involved in managing these interdependencies any longer and top-down decision making processes can be neglected altogether (Peters and Pierre 1998). Obviously government action with regard to funding and regulation has to be an important element in every analysis of biobank governance (see “Biobanks and models for financing research infrastructures” and “Ethics in biobank governance: connecting and separating biobanks from its body constituency”). On the other hand, biobank governance processes have been too often reduced to building a stable legal framework and ethical environment for biobank projects by creating different types of regulation. Cutter, Wilson, and Chadwick have identified two basic models of biobank regulation: first, legislatively created and regulated projects, such as the Icelandic Act on Biobanks establishing the framework for the Icelandic biobank or the Estonian biobank, projects created specifically by statutes and related instruments; second, “self-created/self-regulated projects, like UK Biobank that are created independently from legislation, and interact with existing laws as the situations arise and that are regulated in a self-binding, but not necessarily legally binding manner” (Cutter et al. 2004). Both trajectories suggest that the establishment and operation of a biobank; the collection, handling, and access to samples; and furthermore the relationship with participants, research users, and society can be regulated through binding norms, principles, and guidelines.

In this article we introduce a slightly different and broader understanding of the term “governance.” We argue that success or failure of biobanks or, expressed differently, their capacity to produce value, depends on establishing a system of governance, a mode of ordering (Law 1994) that can be understood as a strategy for patterning a network of interaction. This strategy unfolds within and across a number of different fields including a variety of activities that go beyond regulatory activities: the scientific/technological field, the medical/health field, the industrial-economic field, the legal-ethical field, and the sociopolitical field (see Fig. 1).

The processes of problem solving in such governance networks are complex since there is a lack of established systems or procedures of collective decision making. This is true even if there is national legislation in place, since these regulations capture always only a fraction of the relevant issues that come up in a governance network. Therefore, the search for policy solutions becomes inseparable from a search for adequate and legitimate procedures for decision making in the network. Hajer and Wagenaar termed this an “institutional void,” a situation in which

Fig. 1 Biobank governance

“there are no pre-given rules that determine who is responsible, who has authority over whom, [and] what sort of accountability is to be expected” (2003, p. 9).

Moreover, these complexities amplify through efforts to harmonize biobanking practices on an international level, because in these instances even the national regulatory frameworks are absent or widely unknown by international partners. The pan-European Biobanking and Biomolecular Resources Research Infrastructure (BBMRI), a new collaboration of key European biobanks, can serve as one example of this trend. Another is the P3G (Public Population Project in Genomics) Consortium, whose charter members include representatives from biobank projects or cohort studies (including samples larger than 10,000) throughout the world. National collections, it is argued, typically suffer from fragmentation of the biobanking-related research community, and with this fragmentation variable access rules and a lack of commonly applied standards for biobanks. This hampers the collation of biological samples and data from different biobanks, which is a prerequisite for achieving sufficient statistical power (Gottweis and Petersen 2008). Therefore, biobanks—as prototypical research infrastructures of knowledge-based bioeconomies—share some characteristics with infrastructures that have already become ubiquitous in most modern contemporary societies, such as railways, electricity networks, and telecommunication networks. For more than two centuries, such infrastructure development projects have triggered processes of intergovernmental or global governance activities that are complex to grasp since they often cut across territorial jurisdictions and existing political alignments (Held et al. 1999, p. 44ff.). Furthermore, infrastructures in general are mediating the metabolism between the social and its environment (Moss et al. 2008). Thus far their governance has always been a complex issue since it challenges established boundaries of territorial nation states and their modes of legitimate collectively binding decision making, and at the same time undermines assumptions about the boundaries between the natural or technical and the world of the

social and the political. This is especially evident in the case of biobanks and transnational biobank networks, which mediate the relation between societies and increasingly valuable biological materials with attached lifestyle and health information (Lauss 2009). It is precisely the establishment and interactive management of this type of network or, more precisely, this network of ordering that encompasses everything from technical details to cultural factors that we consider to be crucial for the success of biobanks. Such networks are strategic, established over time, always in need of ordering interventions, and increase their stability through building in a certain degree of flexibility. Governance structures emerge out of these processes that include a variety of microsocial interactions and coordinating activities within and across these different fields (Mayrhofer and Prainsack 2009).

Governing scientific and technical harmonization and the assembling of a scientific community

Biobank projects involve scientific technological ordering processes in which complicated research networks are created, links between broad varieties of factors are established, and an effort is made to create a certain amount of stability through standardization, normalization, establishment of protocols, data warehouses, databases, and identification of strategies for how to link patients/participants with research, analysis, and interpretation. Still in its early years, most debate about biobank development focused on large national projects that collected mainly blood samples and DNA (such as in Estonia or Iceland), whereas tissue collections were established in a fragmented manner, resulting in tissue banks of variable size, composition, standards, and with different goals (Kaiser 2002; Cambon-Thomsen 2003; Hirtzlin et al. 2003; Hagen and Carlstedt-Duke 2004). In principle, biological materials such as blood samples and different types of tissues are potent and complex information carriers. For experts who know how to interpret morphological, biochemical, and genetic variation, they are windows for understanding the processes that lead to disease. Different analytical technologies are available in order to extract this information. But the scientific validity of the resulting data obviously depends on the way biological materials and data are acquired, processed, and stored, since exogenous factors, such as medical history, medical treatment before and during surgery, time to preservation (ischemia), and sample processing, can affect molecular data.

Both population-based biobanks and biobanks using biological specimens involve highly complicated, expensive, time-consuming, and intricate processes of accessing, collecting, storing, analyzing, and interpreting biological samples. While these processes are inseparable from

society, politics, ethics, law, and the economy, they are in aggregate an enormously difficult operation that requires a high level of scientific competence, technological equipment and know-how, and the diligence to avoid the many mistakes that might occur.

Population-based biobanks need to carefully build a link between individuals to be part of the planned study and the biobank to be constructed. The identification of potential participants involves, for example, in the case of UK Biobank, setting up national health service assessment centers, creating a standardized protocol for accessing potential participants, writing questionnaires, sending out invitation letters, training assessment center staff, establishing an assessment center monitoring process, developing a fully integrated IT system, and devising and implementing medical checkup and sample collection procedures (UK Biobank 2003). Just as with biospecimen collections, population-based biobanks involve extensive preparation and coordination processes to create the kind of research tools envisioned by their creators and funders.

Biorepositories that collect tissue that is removed during routine medical care such as surgery or diagnostic procedures face slightly different challenges. The process governing such tissue involves a variety of personnel, such as pathologists, pathology assistants, histotechnologists, tissue technicians, and trained repository personnel (Eiseman et al. 2003). It is crucial to order the workflow of these myriad of professionals in order to assure researchers' trust in sample quality. Biobanks are institutionalized service providers to researchers by relieving them of the process of sample acquisition, thereby also separating such acquisition from the experimenters, which utilize the research material. Furthermore, the demand for samples in many large research projects is too great to be satisfied by just one biobank and it became clear that some minimal standards across biobanks were needed regarding sample quality and documentation. Quality assurance is therefore a fundamental component for operating any biospecimen collection (ibid., p. xxi). Developing standardized protocols for a variety of routine activities such as sample documentation is key in this context. Because sample qualities that are important for one research question and methodology are often of no or only minor relevance for other research purposes, it makes sense for biobanks to have samples with different qualities. It is therefore essential that accurate systems of documentation are in place that permit later assessment of sample properties. Here the documentation process becomes important because it helps to decide researchers which samples can be integrated into which study designs. This flexibility makes integration of different biobanks possible. The integrative process is not universal but rather is selective in the face of different research projects in which samples can be utilized. Some documentation has to be done during or shortly after the sampling process.

However, it is not feasible to determine all possible parameters *a priori* and include them in a huge data bank. Often this has to be done when biological samples shall be utilized in a research process and before they are selected for particular experiments. Regular training programs for the biobank and hospital staff that is involved in the collection, processing, annotation, storage, and distribution of tissue is therefore as important as the development of standard operating procedures. Moreover, the relationships between the various types of personnel need to be defined, such as the role of the pathologist to confirm the identity and diagnosis of biospecimens collected by the biorepository. Standards for the storage of tissue and for monitoring the specimens around the clock need to be developed. A bioinformatics system has to be developed, and at that point, questions of data access and data protection must already be taken into account. Because each of these steps in handling, describing, storing, and retrieving biospecimens involves a broad mobilization of knowledge and resources, and each of these steps can go wrong, the ultimate usefulness of the biorepository under development inevitably comes into question, if too many inconsistencies occur.

Since these are techno-scientific matters, it is impossible to regulate these issues in a top-down manner. Nevertheless, some order has developed in these fields, and coordinative measures have been promoted by scientists and science funding agencies. From the point of view of research governance, this involved organizing research communities into international projects like BBMRI, P3G, and Promoting Harmonisation of Epidemiological Biobanks in Europe (PHOEBE), which have addressed harmonization issues in recent years. With the financial resources and organizational structures provided by a variety of funding agencies and universities, it became possible to assemble a critical mass of practitioners into communities of practice (Wenger 2000). Such communities of practice will be needed in order to utilize biobanks for biomedical research purposes in the future. The outcome of these governance processes is not a piece of regulation that sets a “gold standard.” The strategy is to create spaces in which mutual understanding, learning, and trust could occur between different experts. How to enable these ongoing integration processes in these fields will be a critical governance issue for science funding agencies and research communities in the future.

Biobanks networks extend into fields of medicine and health care

In many cases, the successful completion of biobank projects depends on the evolution of patterns of cooperation with the health care system, its given structure, and its current development (Brown and Webster 2004). Therefore,

the research network biobank must become a broader network stretching to a variety of nodes such as medical schools, hospitals, and health care provision. This is not always an easy process, as it involves incorporating and interacting with a broad variety of groups, from geneticists to doctors in different hospital departments that provide patient records or blood samples.

The lengthy process from procuring tissue samples or blood to analysis is almost impossible to complete without some friction or conflict. It should not be expected that the medical system or health care providers are necessarily enthusiastic supporters of biobanks. Biobanks potentially constitute significant interventions in the daily life of a hospital or medical school and imply transformations of health care provision and research practices that are not necessarily welcome by all actors. There are no clear-cut solutions for how to connect and integrate biobanks with the healthcare system, but this process is crucial and currently much experimentation ongoing in different biobank projects worldwide. In Iceland medical practitioners felt “dispossessed” by the project as it was originally designed in the framework legislation for the “health sector database” (Fortun 2008; Palsson 2008). Similar experiences—although on a smaller scale—have been made in Sweden (Hoeyer 2006) and Austria (Metzler 2010). This suggests that the probability for conflicts and resistances are especially high in situations in which motives of commercialization are interwoven with the research processes in which samples and medical data are utilized. Especially under these circumstances, it is important for a biobank to develop transparent rules for the access of samples and data. This has to be done from the beginning in an inclusive way that takes into account the medical staff’s sensitivities and their notions of fairness. This is especially important since at the end of the day, this bridging between the research network of the biobank and the medical context constitutes a key resource for translating basic research into application, such as the development of new drugs or diagnostic purposes.

Another example for difficulties in the realm of funding, financing, and commercialization is Japan. Despite backing and financing by the government, Biobank Japan was promoted almost exclusively by private hospital groups rather than by large public university hospitals. When the Biobank Japan project was first announced, members within the Japanese scientific community, including leading geneticists, expressed surprise at or even anger with the decision by the ministry of education to fund the project. Biobank Japan early on had chosen not to seek contributions from prominent public universities and medical schools, instead enrolling a number of private hospital groups to participate. Engaging medical schools at the University of Tokyo or Osaka University would have meant

a complex process of consultation that eventually would have almost certainly led to a fragmentation of project leadership. Keeping sample and information collection simple was a key strategy. Thus, Biobank Japan does not collect tissues but instead collects only peripheral blood, which can be obtained in a very short period of time. Further, clinical information is partly processed and is entered into a highly standardized format by Biobank Japan's own staff, rather than by participating hospitals, thus eliminating possible bottlenecks and other problems. While doctors need to refer patients to the consultation room, the sampling work is done by the hundreds of medical coordinators at the various hospitals (Triendl and Gottweis 2008).

One model for cooling down heated situations has been developed in the Estonian case. Here incentives have been provided to general practitioners (GPs) that were expected to play a key role in linking the biobank project to the health care system and thus in the envisioned establishment of a novel system of preventive medicine. The integration of GPs into the Estonian Genome Project (EGP) was one of the successes of the project in its early stage. A central motive for their participation in the project seemed to be the prospect of GPs being part of a prestigious medical–scientific project. Furthermore, the GPs received a strong incentive to participate, as all GPs in the project received IT equipment such as personal computers to be able to process the collected data. In addition, each GP received a financial compensation per donor (Eensaar 2008). Although this is clearly not the only promising instrument in dealing with the problem presented in this section, a good deal of the energy that has to be invested in planning and managing biobanks and biobank networks should be dedicated to thinking about appropriate monetary and nonmonetary incentive schemes, which motivate professionals and lay participants.

Biobanks and models for financing research infrastructures

Biobanks potentially create commercial value or “bio-value.” Catherine Waldby has interpreted the economic value of biotechnology as biovalue and defined it as “the surplus of in vitro vitality produced by the biotechnical reformulation of living processes” (Waldby 2002). Not surprisingly, ownership and patenting have become major topics in the discussion on genetic databases. Access, control, and ownership of biobanks and the question of property rights were in particular central issues for those projects in which private industry played an important role (Björkman and Hansson 2006). However, it is important to see that issues of commercialization are closely linked to

the ways in which biobanks acquire funds. To set up a biobank and to keep it, operating tends to be costly. They swallow up large amounts of money for the costs of the facility, storage expenses, and personnel alone, and these costs run over long periods of time. Such expenses do not support research as such but finance research infrastructures and tools of research; such costs are not easily carried by research funding bodies, universities, or other funding sources, such as research ministries, which tend to fund basic or applied research directly. Thus, any biobank needs to have a solid financing model that provides for both its initial setup and its operation over time. It also needs to fit into the national innovation system and its characteristics, such as the availability of venture capital, or the structure of the pharmaceutical industry. Biobank governance thus needs to develop a strategy for how to link the research network of a biobank to the worlds of potential supporters and funders. In the following we will present three different types of ordering in this domain: (a) the entrepreneurial biobank model that is often carried out in a public private partnership between a commercially oriented entity and different state institutions; (b) the biosocial model in which patient activist groups promote, fund, and facilitate the creation and operation of a biobank; and (c) the public biobank model in which biobank networks are supported mostly through taxpayers money and nonprofit research funding organizations.

Entrepreneurial model

Economic arguments were crucial in building political support for genomics, personalized medicine, and biobanks. In some countries, including Israel and Iceland, narratives of genes as national assets coexist with privatizing tendencies in biobank development (Gottweis and Petersen 2008). Early attempts to create biobanks in Iceland and Estonia followed the model of a public–private partnership that has become a popular strategy in public administration during the 1990s (Pollitt 2003). However, this strategy turned out to be more challenging than originally envisioned.

Iceland's biobank was created without government financing, instead being funded by deCODE Genetics, a company founded in 1996 by Icelander Kári Stefánsson. The project soon created controversy, and debates within Icelandic society focused on issues of property, ownership, and control. Many Icelanders, in particular professional groups and medical practitioners (see “[Biobanks networks extend into fields of medicine and health care](#)”), found it appalling that a private multinational company would have access to genetic information and medical records and would then explore the genetic bases of common diseases in the Icelandic population and be able to commercialize the results (Pálsson 2008). But deCODE Genetics received

the license to construct the genetic database in return for a fee paid to the public health service sector; thus, a private model of biobank financing was created. However, the original plan was never fully realized, and deCode Genetics Inc. filed for bankruptcy in 2009 (Check Hayden 2009).

The Estonian Genome project developed with a combination of public and private funds. In 2001, the government provided initial funding of 64,000 euros for creating a public foundation [Estonian Genome Project Foundation (EGPF)], but EGeen, an Estonian company owned by the EGPF and EGeen International Corporation (EGI), which was located in the USA, provided financing for the preparation and establishment of the biobank during 2001–2002. In return, the company received an exclusive 25-year commercial license for using anonymous data from the biobank. In 2003 the first conflicts in this consortium began to emerge. EGI said it wanted to concentrate on specific disease groups such as hypertension, and it also casts doubt on the quality of collected data of about 9,000 donors. The conflicts between the EGPF and EGI continued during the next year. Finally, in November 2004, the exclusive license and financing contract with EGeen and EGI was terminated, and the EGP, no longer tethered to a commercial entity, was able to seek public financing. Finally, in 2006, the Estonian state made a decision to support the project in the future (Eensaar 2008).

Although the EGP early on linked the biobank project with public health and established a good connection between societal needs and the operation of the biobank, its initial business model failed soon after the project was launched. The ensuing crisis accentuated the need for a viable business model for any biobank project. Although the EGP was intended as a way to launch the Estonian biotechnology industry, this sector was still too nascent for the plan to be effective. In addition, Estonia had little national venture capital prepared to invest in the EGP, which forced the EGPF to seek foreign venture capital to invest in a project whose commercial value was uncertain (Eensaar 2008).

Biosocial model

In this model, patient activist groups become active in funding and promoting biobank activities, for example the European Network of DNA, Cell and Tissue Banks for Rare Diseases (EuroBioBank), which has been one of the first operating biobank networks in Europe. EuroBioBank evolved from a civil society movement of French patient organizations, which had formed a biosocial group (Rabinow 1996; Rose and Novas 2004) to fight for a minority health policy for rare disease patients in France, and subsequently coordinated this transnational European networking process (Lauss 2011). At the heart of this endeavor is the private, nonprofit sector

patients' organization, Association Française contre les Myopathies (AFM), which has been active for decades in genetic research, patient care, and legal issues. The two biggest banks of the AFM are the Banque de Tissus pour la Recherche (BTR) and the Banque d'ADN et de Cellules de Généthron (BG), both established in the 1990s, financed completely by the AFM, and governed by the DNA Collection & Banking Department located at Généthron. In 2002, Généthron spent 7% of its 14.6 million euro budget on its bank and collection department (Mayrhofer 2008). The model has proven to be stable. However, it has its limitation, since patient activist groups tend to support research in the disease areas that affect them more or less directly. Their activities are important where public health schemes neglect the biological faith of citizens, because they represent only a very small section of the population (Callon 2005; Lauss 2011). So they are able to correct certain modes of state failure, in cases when practices of state authorities work according to the logics of "big numbers," however they are not democratic practices on their own. Furthermore, patient activist groups are dependent on an ongoing influx of financial donations themselves. Therefore there is a considerable amount of uncertainty involved in this kind of financial support that is dependent on the success of motivating citizens to this type of research.

Public model

Today, economic arguments still play a crucial role in building political support for personalized medicine and biobanks. However, it seems that the entrepreneurial biobank model has lost its gravity.¹ Today biobank projects are mainly supported through public grants and subsidies. Given the crucial role of personalized medicine in the future of healthcare, so it was argued, it was the government that should invest. Shielding the projects from corporate influences often contributes to its political and public relations success by avoiding some of the complex and difficult debates about ownership, genetic privacy, and corporate influences on research that other biobank initiatives have confronted. This model was at the center of Biobank Japan (Triendl and Gottweis 2008), and it was adopted by the UK Biobank as well.² In addition, most of the biospecimen repositories in Europe, such as those located at pathology institutes and hospitals, are also mainly state funded. In the current discussion, state support for

¹ The entrepreneurial biobank model does, however, obviously still exist. One example is the German company Indivumed, which as of this writing seems to remain successful. See www.indivumed.com.

² The UK Biobank is jointly funded by the public health care system (National Health Service) and by a research charity (the Wellcome Trust), neither of which are oriented towards private commercialization.

biobanks has been justified by the argument that biobanks can be seen as a tool of international competitiveness. It has been argued, for example, that Europe with its public health care systems seems to have a strong advantage, particularly vis-à-vis the USA, since the absence of a homogenous national health care system is seen as an obstacle for population-based studies complemented by health data. The challenge in this model is that political support for large, long-term projects can be lost if voters lose their confidence in the promises of genomics or if public confidence in the integrity of biobank and research staff would decline.³

The presence of a solid funding model for securing and maintaining the funding, operation, and utilization of a biobank over a long period of time is crucial. Although private industry has played a role in recent biobank business models, the cases of Estonia and Iceland demonstrate 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 that quickly have raised difficult ethical questions. Other models are based on building ongoing support and trust relationships because the influx of money from civil society is not unconditional as well. Public models—especially in cases like building research infrastructures of biobanks, which will create detectable results mainly in the long-term future and in very dispersed ways—seem to be most likely to secure reliable revenue streams. But support of state authorities cannot be taken for granted as well and will only be sustained as long as there is sufficient convergence between the technopolitical visions of political macroprojects and the biobanks themselves. The BBMRI project in Europe is an instructive example in this respect, because of the way it was amalgamated into the larger process of technical European integration and was able to flourish in the political context of Europe's vision of a knowledge-based society as it was developed in the EU's Lisbon agenda (Lauss 2009). The BBMRI is only one example that shows how crucial it can be for biobank managers to understand and position the biobank in relation to macropolitical rationalities that are able to drive, facilitate, and fund biobanks and biobank networks in the decades to come.

Ethics in biobank governance: connecting and separating biobanks from its body constituency

Biobanks are inseparable from bodies; they help to study data, blood and tissue that are related to or retrieved from participants' bodies and histories and therefore they have to

engage with citizens in their social relations. Establishing and stabilizing the myriad relationships among tissue samples, patient records, blood, DNA- and tissue-donating patients, participants in biobank studies, notions of citizenship, human rights, and general understandings of research and medical ethics are indispensable for any biobank project. It is in this respect that a research network links with society and extends into a broader social network structure. Ignoring the complicated social ramifications of any biobank project can quickly lead to serious problems in its operation. A key issue is how a biobank project socially constructs biobank study participants, donors, and citizens in a way that is compatible with its (macro)political and cultural context. Medical ethics and bioethics are critical discursive resources used in this context (Salter and Jones 2005). Biobank governance is therefore not only a purely technical or scientific matter. The task involves mobilizing different narratives that deal with the questions of what constitutes a human being, an individual, and a citizen. Bioethicists, philosophers, law scholars, theologians, and social scientists engage in this discourse and are engaged in it by the scientists who operate a biobank. The interrelated topics of informed consent, privacy, autonomy, and confidentiality feature prominently in this discourse. The idea of protecting the autonomy of the patient/research participant as an individual and citizen armed with political rights and equipped with the capacity to make informed, rational decisions is at the center of this project. Inherent in this idea is that individuals have the fundamental right to decide about the utilization of their body, body parts, and associated data, and that consent needs to be obtained before any parts or data associated with a particular human body are used (Shickle 2006; Cambon-Thomsen et al. 2007).

At first glance, the idea of informed consent seems relatively straightforward. But the question what amount of information is needed for an individual to make an informed decision in favor of or against participation is not to be answered. In the literature, consent procedures are seen as constituting a continuum from highly specific consent to blanket consent. For biobank research, this could mean that an individual either consents to a specific study to be conducted with his/her tissue, DNA, and data; that consent could be given to do research on a specific disease; or that consent could be given generally, that is, biomedical research permitting use of the sample for any purpose (Hansson et al. 2006; Porteri and Borry 2008). Furthermore, consent is not something that is given once and then cannot be reconsidered. The Declaration of Helsinki, today's authoritative statement on biomedical ethics, states that the consent of research subjects can be withdrawn at any time without reprisal. Closely related to this issue of consent is that of privacy. Over the last decades and in the

³ This could for example happen in the wake of scandals in which biobank staff would pass on samples and information for unintended purposes.

wake of the Human Genome Project, the concept of genetic privacy and the idea of the need for protection from involuntary disclosure of genetic information have gained prominence (Everett 2003, 2004). In the recent years, this issue has been tackled by developing sophisticated IT solutions to anonymize data (Machanavajjhala et al. 2007; Stark et al. 2007).

As important as these IT-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 less clear than is evidenced in much of the existing literature on the topic. Newly developed technologies such as high-throughput, low-cost sequencing are applied increasingly to human genome and phenome data sets. Comprehensive data sets establish informatics links among genome sequences and extensive phenotype analysis thereby enabling the identification of individuals whose DNA sequence they contain. The data flood that results from modern genomics have in a certain sense led to a reevaluation of old, well-established bioethical principles. As Caplan and Elger argue: “After 50 years of classical health research ethics, regulatory agencies have begun to question fundamental ethical milestones” (Elger and Caplan 2006, p. 664). In two remarkable articles, Lunshof et al. systematically examine the key concepts of medical research ethics, consent, privacy, and confidentiality and diagnose that these concepts are currently stretched to their limits since absolute data security can no longer be guaranteed. They argue in favor of open consent and emphasize veracity: “We believe that the building of any comprehensive genotype–phenotype data collection requires that the individuals from whom these data are derived be fully aware that the data can be and likely will be accessed, shared and linked to other sets of information, and that the full purpose and the extent of further usage cannot be foreseen. Individuals should realize that they are potentially identifiable and that their privacy cannot be guaranteed. Full and valid consent by the participants requires veracity on the part of the researchers as a primary moral obligation. . . . Open consent means that volunteers consent to unrestricted redisclosure of data originating from a confidential relationship, namely their health records, and to unrestricted disclosure of information that emerges from any future research on their genotype–phenotype data set, the information content of which cannot be predicted” (Lunshof et al. 2008a, b). The philosophical justification of this argumentation can be found in the communitarian turn in bioethics, as expressed, for example, in an article in *Nature Review Genetics* by two of today’s leading bioethicists, Bartha Maria Knoppers and Ruth Chadwick, in which they argue that it is time “to rethink the paramount position of the individual in ethics.” The authors continue

in their discussion by approvingly quoting a recent WHO report on genetic databases that states: “The justification for a database is more likely to be grounded in common values, and less on individual gain. . . . It leads to the question whether the individual can remain of paramount importance in this context” (Knoppers and Chadwick 2005, 75). Knoppers and Chadwick develop their argument by discussing “new ethical principles” such as reciprocity, mutuality, and solidarity as possible strategies to go beyond the more traditional “individual-centered” approaches in ethics. Thus, the communitarian ideal of the public good seems to overshadow the “classical” ethical orientation towards individual autonomy. It seems that in the face of mounting difficulties in biobank projects to deal with individual-centered approaches in ethics, such as in informed consent, bioethical ideology has already begun to develop a “new pragmatism” (Knoppers and Chadwick 2005). However, what counts as “public good” has to be repeatedly negotiated in pluralist democratic societies and cannot be taken for granted (Gottweis and Lauss 2010). This issue is especially pending in transnational biobank infrastructure networks, since we (as we have argued before) have to operate in an “institutional void” (Hajer and Wagenaar 2003; see “[Understanding biobank governance](#)”) in which there is a lack of procedural certainty on how to reach agreement on what constitutes a “public good”—and we do not even have a clear idea what constituency would be able to decide this delicate issue. Hence, linking biobanks with citizens and patients is hardly an easy project that can be built on well-established principles and experiences alone. Scientific and technological advances and the growing importance of cross-national cooperation indicate that well-established medical–ethical procedures that used to work well in the field of clinical trials have been reshaped for the field of biobank research networks. This not only raises a whole range of new theoretical–conceptual issues but also poses the question of the sociocultural acceptance of these possibly newly arising ways of biobanks connecting with different (groups of) individuals.

Biobanking and the politics of democratization through public engagement

A wide spectrum of codecision makers are always part of a governance process. However, these actors differ with respect to their resources, in terms of their power base and the level of their social connectedness. Like in other “pluralist heavens,” the flaw is often that the heavenly governance chorus “sings with an upper-class accent.” (Schattschneider 1960, 35) There are nearly always asymmetries in network governance arrangements. Further-

more, steering processes of technological arrangements tend to look very democratic and liberal from the inside, but appear to be very exclusive clubs from an outside perspective (Barry 2001, 53). In order to open up the closed circle of traditional (expert) stakeholders, some efforts have been made to develop more inclusive approaches in biobank governance during the last decade.

In the past, biorepositories tooled along quietly, perhaps in the seclusion of pathology institutes. However, with the reevaluation of existing biobanks and the creation of new ones, multifaceted medical–ethical issues have arisen along with more general sociopolitical issues, such as the perception and the acceptance of biobanks in society. As recent history tells, biobank projects are not necessarily warmly received by all social groups and even can collapse due to social resistance. In this respect, the political–cultural context of any biobank project plays a very important role. While the construction of the participants/patients in biobank projects is a topic of paramount importance, it is important to recognize that most citizens do not belong to this social group. Thus it is a critical element of patterning biobank networks to establish stable links with different “publics.” Especially in “life–political issues,” the notions of participation and governance have become intermingled to an unusual extent (Gottweis et al. 2008). However, one problem with “the public” is that it is not a fixed entity that governments or biobank managers can simply reach out to and invite to participate in some way in the deliberation of a biobank project. Even though, publics (of biobanks) can still spontaneously emerge around issues (Marres 2005; Dewey 1991 [1927]) and are shaped by the actions of any number of activists who problematize a particular topic, “publics” in most participatory arrangements tend to be at least coconstructed and shaped top-down by state authorities.

In cases in which “spontaneous” publics emerge, participants have not been “invited” by government institutions nor have they been selected by formal “organizers”; on the contrary, actors are self-selected or “self-appointed” and as such have usually entered the debate from a partisan point of view that promotes their respective cause. Public involvement that takes place at such unexpectedly politicized sites and is led by civil society rather than by the state tends to feature a rather antagonistic structure, characterized by sometimes adversarial arguments and struggles. In Iceland, an “unruly” and “spontaneous” public acquired a key role in a biobank project, when a strong ethical and political body Mannvernd—the Association of Icelanders for Ethics in Science and Medicine—was formed in direct response to the database project (Fortun 2008; Palsson 2008). While deCODE genetics had developed a business plan and a scientific vision for its biobank project, the company was not prepared to engage in a (critical) dialogue with diverse social groups. Consequently a gap

between some parts of the Icelandic civil society and deCODE emerged and at a certain moment it became impossible to bridge that gap. The difficulties in developing the Iceland biobank probably prompted the UK Biobank’s extensive efforts to connect social groups and civil society organizations with the biobank. In 1998, when proposals for a UK genetics population database first emerged, the actors involved in the project realized that ethical considerations would need to be a central concern. The developers of the project determined that they would support a position in which the biobank could be accessed by commercial entities but that this access would be subject to adherence to strict ethical protocols. Furthermore, the biobank project would be a public venture funded by UK medical charities and government departments (Corrigan and Petersen 2008). In this strategic move, participation was used as a governance instrument that helped to organize or construct different “publics” in order to make deliberation with different stakeholders possible. The funding agencies were aware that the biobank project would need to gain the support of not only the half million proposed participants but also the population at large. The Interim Advisory Group (IAG) was created in 2003 and charged with providing a formal ethics and governance mechanism to regulate the UK Biobank project. The IAG was also the advisory body to the UK Biobank’s funders on the best ethical practice to be designed to provide a sound basis for fostering public trust and confidence in the project. The goal of the IAG was as much about minimizing the risk to the project of public rejection and ensuring public trust as it was in minimizing the risks of harm to those participants involved in the research. The Ethics and Governance Council is now permanently established to act as an independent guardian of the UK Biobank’s Ethics and Governance Framework and to report to “the public” about the UK Biobank. The project partners have made much of their efforts to “consult” “the public” and pertinent stakeholders. These include panels and workshops involving members of “the general public” from across the UK and specific groups (e.g., people with disabilities or diseases and religious and community groups), meetings with industry and focus groups with primary healthcare workers (Corrigan and Petersen 2008). Apparently, the UK Biobank had gone through extensive considerations for how to link society with a biobank and used a broad range of instruments to implement this process. This does not turn the UK Biobank into a blueprint for other biobanks all over the world, since obviously this type of interaction with society or publics was very much designed for the UK context, its administrative and political institutions, and the existence of a rather demanding civil society. Nevertheless, there is a message to take from these efforts. It cannot be taken for granted that societies are always in favor of all types of scientific projects, especially if such projects are large in scale. This is

especially important since biobanks are very much dependent on taxpayers' money and therefore also on political support. From that insight it is "time to acknowledge diversity" (Hoeyer 2010) of different biobank constituencies in different setting all over the world. Different biobank projects need to find different ways to engage with their social environment and will have to make their own experiences in bringing together the most relevant "publics." To integrate different points of view and preference and to canvass for support will be important tasks in biobank governance in the future.

Conclusions

Failure of biobank governance occurs when the technosocial network is no longer able to generate support and is unable to produce value. We proposed that biobank governance be understood as a patchwork strategy for ordering a network of interaction that unfolds along a number of different fields, the scientific/technological field, the medical/health field, the industrial–economic field, the legal–ethical field, and the sociopolitical field. This "ordering" cannot be designed in a top-down manner. It is dependent on many dispersed inputs from a variety of actors that understand their mutual interdependence. Bringing order and stability into such a relatively open and not always well-defined network is the key challenge for today's governance of biobanks. Our account emphasized that biobanks are not technical visions that operate vis-à-vis an external society. Biobanks are a part of society and are essentially constituted by the manifold process of networking heterogeneous elements into a system able to meet the rising appetite for biomaterials that is part of the genomics adventure at the beginning of the twenty-first century. Although we proposed that biobanks be understood as a network structure that is not only a research network but a more extensive network that operates through a variety of nodes in different fields from finance to society and bioethical discourse, this does not mean that all the different issues are pending with the same intensity all the time. Biorepositories of universities might collect disease tissue over long periods of time mainly for internal purposes and might not be in need of substantial outside funding nor be under pressure to develop extensive exchanges with different social stakeholders. But this situation might change quickly when the goals change and the mentioned biorepository begins to develop cooperation with industry or with international research partners. Likewise, public sensibilities towards topics of medical research and development change over time and are different from country to country. Business models that work well in certain periods of time are doomed in others. It is important to understand

these challenges in their complexity, interactivity, relatedness, and dynamism. Only then can the ambition of biobank research be translated into the creation of value for research, health, and industrial applications in the medical field. Although these attempts to facilitate and manage the integration of a network of more or less interrelated actors should not be equated with democratization per se, they can be regarded as steps towards a more pluralistic and inclusive style of policy making.

Acknowledgments The research for this article was conducted in the context of the projects "PRIVATGen" (Privacy Regimes Investigated: Variations, Adaptations and Transformations in an age of (Post-) Genomics) and GATiB II (Genome Austria Tissue Bank), which are both supported by the Austrian Genome Research Programme (GEN-AU). The authors would like to thank the funding agencies that made this research possible. In addition the authors would like to thank the members of the LSG for the stimulating research environment they provided and their useful comments.

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