

Embracing complexity and uncertainty: An analysis of three orders of ELSA research on biobanks

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Abstract

During the past decades, research on ethical, legal, and social aspects (ELSA) of biobanks suggested and analysed various ethically and socially justifiable frameworks for collecting, storing, and distributing human biological material and bioinformation. In this article, we identify three patterns of argument that differ in terms of shared core assumptions and similar conceptual as well as normative orientations. These discursive ‘orders’, which are related to specific macropolitical contexts, have significantly shaped contexts for biobank policymaking. The first order was characterised by high expectations of genomics and biobanking. Second order discourse partly took over the problems located in the first order, but reintroduced them into a justificatory framework that identified biobanks as public goods *per se*. The third order of ELSA expertise maintained a supportive attitude towards biobanking. However, regulation based on deductive reasoning became progressively complemented by ideals of participatory mechanisms and different methodologies of studying public perceptions. We conclude that this emphasis on learning processes and deliberation helps biobank communities to develop new concepts, methods and insights that will prove helpful in order to adapt to essentially undetermined futures of transnational innovation societies.

Introduction

The role of ethics in policy discourses about biotechnological innovation has already received a reasonable amount of attention.² Building on this, in this article we critically discuss the emergence of three ‘orders’ of research on ethical, legal, and social aspects (ELSA) of genetics and biotechnology, as it has developed with regard to biobanks in the past 15 years.

We assume that the language of this ELSA discourse, like language in general³, does not simply mirror the world but shapes our view of it in a profound way. The space of biobank policymaking is therefore *ordered* by analysts’ ways of representing a policy or policy problem. These representations are necessarily selective and make assumptions about “causality and responsibility, about legitimacy and authority, and about interests, needs, values, preferences, and obligations”.⁴ Our analysis of discursive practices or orders focuses on how particular narratives privilege some issues or things over others and on the ways in which the language of ethical analysis itself not only depicts but also constructs the issues it deals with in a particular manner.

We identify two major transformations in ELSA research on biobanks and consequently three ‘orders of ELSA expertise’, whereby the concept of ‘order’ points to a change of emphasis in what counts as a concern in ELSA expertise. However, the orders we introduce have not replaced each other. Rather, they overlap, complement and superimpose each other. Therefore, our distinction is not meant to highlight clear-cut historical changes but to try to deliver a conceptual framework to detect shifting trends and offer some explanations for each of the changes that are routed in wider governance paradigms.

We will argue that the first order of ethical assessment of biobanks was mainly critical in tone. To some extent, this was a reaction to market-oriented visions and very optimistic – perhaps too optimistic – expectations about the value of novel biobank projects.⁵ As a consequence, ELSA research focused on issues such as the protection of donors’ privacy and their rights, which were debated in a situation of regulatory uncertainty about the operational requirements of biobanks.

The second order of ELSA expertise responded to the problems raised in the first order. Development of national regulation and international harmonisation introduced regulatory solutions to many ethical, legal, and social concerns of biobanking – the procedure of informed consent being the most well-known example.⁶ However, different types of privacy problems have still been the constant companions of biobank projects during the last decade. Moreover, the second-order expertise adopted a paradigm in which biobanks have been conceptualised as a ‘public good’ and donating tissue and data was framed as an act of solidarity.⁷ We argue that the viewpoint that biobanks represent a public good *per se* became widely accepted, and this consensus about the value of biobank research resulted in the framing of opposing arguments as issues of privacy – generally acknowledged public good can be contested by referring to private rights.

This project of the second-order ELSA research has been effective. It helped to absorb a great deal of uncertainty in a phase when biobanks turned from ‘expensive visions’ into ‘expansive practices’ and proved to be capable of being quite stable sociotechnical arrangements. At the same time, the growing complexity of transnational biobank projects, new uncertainty about the value and outcomes of these projects, and ongoing debates about benefit sharing,⁸ privacy,⁹ and types of consent¹⁰ have triggered what we call the third order of ELSA expertise – new procedural and reflexive configurations in governing biobank infrastructures and their utilisation. The last section of this article shifts attention towards this third order that we identify on the horizon of ELSA discourses: an order that accentuates reflexive awareness of ambiguity and continuing reexamination of regulatory standards.

Methodological remarks

For the purpose of this article we have collected and read a broad range of articles that addressed ethical and governance issues in relation to the practice of creating and running biobanks. These appeared mainly in a) social science or humanities periodicals b) ‘life science’ journals in which these kinds of articles mainly appeared

as commentaries or opinion pieces, and c) edited volumes on biobank topics. Moreover, our analysis included texts that have been intensely referenced by academic articles – mainly project reports and statements of regulatory or ethics bodies. The material has been gathered through extensive literature searches and has been compiled in an Endnote[®] database consisting of more than 500 articles dealing with biobanks and related life science issues.

An initial analysis of the database clearly showed that the issues of ‘privacy’ and ‘consent’ have accompanied biobanking for more than 15 years now. In the re-analysis of the material we concentrated on different ‘justificatory logics’¹¹ in the field of biobanking where these main issues were addressed. We then made an effort to discover patterns of argument that would share core assumptions and would show similar conceptual and normative orientations. As we will demonstrate, we found that it was possible to group the justificatory logics according to three different discursive orders that appeared to be linked to different conceptualisations of the ‘public’, and thus the ‘public good’, on the one hand, and to changes in the basic social role or self-understanding of the ELSA community on the other hand. We do not claim that our analysis captures everything that has been published in this domain, but we suggest that our analysis, building on our database, reflects the most relevant lines of the debates we were interested in.

Biobanks as sociotechnical arrangements

The term ‘biobank’ refers to a variety of social and technical arrangements for the collection, storage, and exchange of biological materials and associated medical and lifestyle information. While collections of biological materials, e.g., pathological collections, are as old as modern biomedicine, with the inception of molecular medicine in the late 1990s such collections have garnered new interest.¹² It was widely argued that establishing large collections of tissue samples and enriching these materials with clinical and medical data and lifestyle information could significantly improve or even ‘revolutionise’ biomedical research and enable a new understanding of complex diseases.¹³ The launch of the first big, population-based biobanks in Iceland, Estonia, and the United Kingdom triggered intensive bioethical debates and controversies. A decade after these controversial beginnings, biobanks seem to have acquired stability. They are no longer as controversial as they used to be, and they operate in an increasingly standardised administrative and legal context. They are widely recognised as an important infrastructure for biomedical research and can act as research-infrastructure hubs¹⁴ in the knowledge-based bioeconomy.¹⁵ At the same time, new challenges are emerging as biobanks move from the national to the international scale. Indeed, while in the past a single biobank of sufficient size seemed to be the only essential, nowadays the capacity for connectivity in – increasingly international – biobank networks seems to be at least equally important. Indeed, efforts to create transnational biobank networks have been institutionalised all over the world.¹⁶

Maintaining a biobank requires assembling numerous people, organisations, and technical procedures in a legitimate manner. The normative issue of any biomedical

research today, namely ‘how people should be gathered into the research process?’¹⁷ has become a highly complex one in relation to the establishment and maintenance of biobanks and biobank networks. ELSA research on biobanks has addressed the questions and solutions through the framings that we call ‘orders’, which have suggested different ethically and socially justified procedures for collection, storage, and distribution of biobank material.

The first order – high expectations of genetics confront opposition and concern

During the 1990s, many bioethicists and social scientists were concerned about the implications of the very optimistic scientific expectations of genetic medicine and associated pursuits for commercial exploitation of biological material and medical information being collected in national biobanks. A critical – even dismissive – approach evolved as a core element of the first order of ELSA research on biobanks. To some extent, the concerns typical of the first order of ELSA research were shaped by the first biobank initiative that gauged broad interest: the biobank project in Iceland.

The Icelandic biobank project, based on a partnership between the private company deCODE genetics and the Icelandic government, became a central point of reference for an international debate about the ethical, juridical, and political problems of biobanking. deCODE genetics was envisaged as a major ‘road-building project’ for medical genetics, parallel to the Human Genome Project (HGP), which epitomised molecular genetics as ‘Big Science’.¹⁸ The aim of the Icelandic project was to integrate three databases: genealogical records, medical records collected in public healthcare, and a database of blood samples for genetic analysis. The project provoked opposition both inside Iceland and outside the country, although for different reasons. Importantly, most critics were not against biobanking in general; what was opposed was the particular way in which this biobank was organised, the overtly commercial emphasis, and the proposed public-private partnership model.^{19, 20}

Within Iceland, the main opposition to the biobank project came from Mannvernd, the Association of Icelanders for Ethics in Science and Medicine, and its main spokespersons were physicians, biologists, geneticists and philosophers.²¹ Paralleling Cook-Deegan’s account of the politics of the HGP,²² the struggle was most intense within the scientific and medical community itself and was mainly about the right structure for such a research infrastructure project, the right way to do science in general, issues of patentability, and the importance and effects of different strategies of commercialisation. However, the main proponents no longer exchanged their arguments in a purely academic setting, where they would argue in order to convince their respective opponents. The debate had become public and the rationale was to win over the support of large parts of the population. The opposition propagated the fear that the project was running under unfavourable conditions either for the general population or for individual citizens. However, it seemed that the supporters of the project were able to win over more allies than their counterparts. A Gallup survey in April 2000 showed that more than 80 per cent of the Icelandic population was in favour of the project.²³

The critics resorted to well established bioethical and juridical principles that had their roots in post-Second World War medical ethics and focused on the protection of subjects and patients in experimental research and clinical trials. They emphasised infringements of informational privacy on the one hand and decisional privacy or autonomy on the other hand.^{24, 25} This focus transcended the domestic realm. Subsequently, the international debate on the Icelandic biobank project tended to spotlight issues such as exploitation, data protection and informed consent.²⁶ In particular informed consent, the contract-like, individual approval of the use of samples and data in a variety of research projects became presented as *the* solution to the ethical problems in other national biobank initiatives, also serving as the means to legitimate biobanking.²⁷

However, the idea that large-scale biobank projects burdened with scientific and commercial expectations could not be fully examined by these 'old' tools, was now gaining prominence.^{28, 29} It seemed that the existing standards of medical ethics did not fit into the new organisational form of technology any longer, and a lack of adequate regulation was diagnosed. From these starting points, the first-order ELSA expertise focused on protection of the individual and privacy through better regulation. The new regulatory efforts were also a reaction to a market-oriented liberal strategy promoted by the proponents of the Icelandic database project. The second-order of ELSA expertise grew from the identified problems and discrepancies in ethical and legal regulation.

The second order – securing donations through regulation and the promotion of biobanks as public goods

The Icelandic project was followed by other biobank projects in the UK, Estonia, Germany, France, Austria, Japan, Israel, and several Scandinavian countries.³⁰ The establishment of big national biobank projects like the UK Biobank and the development of biobanking activities toward transnational information networks (e.g., BBMRI) coincided with the shift from genomics to postgenomics and a new focus on 'genomic diversity' after the HGP was completed.³¹

As the new approaches in molecular medicine required both larger amounts of and more diverse data, the demand for stable systems and arrangements for the circulation and exchange of research data and associated medical information across national borders became more intense.

The expansion of national biobanks and the launch of transnational biobank networks in the first decade of the 21st century, especially in Europe, took place under the influence of the macro-political discourse of the so-called 'knowledge-based economy' in which governments all over the world stressed the importance of scientific knowledge as a factor of production. The goal has been to promote economic development and population health through promoting science.^{32, 33} Biobanks can be regarded as one practical realisation of this policy agenda at the national and transnational levels.^{34, 35} On the European level their institutionalisation

became connected to the programme of the European Research Area (ERA) and the subsequent establishment of the European Strategy Forum for Research Infrastructures and most important through several funding opportunities for European research infrastructures in the 7th Framework Programme of the European Union.

On the European and on national levels the activities for building ‘infrastructures’ for biomedical research were now more directly governed by public-sector funding bureaucracies than in the Icelandic case. At least, direct investment and involvement of for-profit businesses in biobanking was the exception rather than the rule.

It seems to be possible to situate the changes in biobank policy discourse in these larger developments. As a consequence of these techno-scientific and political-economic shifts and as a reaction to the problems of perception that ordered the policy space in the first phase of biobank expansion, new ways of addressing ethical, legal and social issues emerged and stabilised in what we term the ‘second order’ of ELSA research on biobanking. This order never replaced the first one altogether. In particular, concern over privacy problems continued to be a focus of ELSA discussions. However, while the first order of ELSA research was antagonistic and highly critical, the emerging second order of ELSA expertise seemed to be more lenient toward biobanks. Many ELSA experts seemed to be confident that biobanks were *per se* important tools to promote science, and in line with the key features of the discourse of the knowledge-based economy, tended to assume that this would lead to improvements in public health and overall well-being of society.³⁶

The tone of the academic commentaries started to change. Biobanks began to be framed as ‘public goods’, and there was an ongoing commitment to promote their public acceptance.³⁷ While the first order had identified possible problems and risks associated with biobanks, the new ELSA academic discourse turned toward a pragmatic rationale and focused on finding solutions to problems such as data protection, more adequate procedures of informed consent, and governance models.^{38,39,40} The underlying vision was that firm moral and juridical principles developed by experts in bioethics and medical law could provide the foundations for regulations and guidelines that, in turn, could make the nontechnical dimensions of biobank infrastructure manageable. This work was seen as instrumental in fostering the social robustness of research⁴¹ and in providing research projects with the authority they needed in order to operate successfully in the current political and economic environment. The aim was to stabilise biobanks by increasing regulatory certainty. Biobanks had transformed from an unsettling source of concern to resources that could be properly managed. ELSA expertise, it was argued, could help in this endeavour. In this context, many ELSA experts adopted the term ‘governance’ to refer to legally and ethically sound management of biobanks.⁴²

This new order of ELSA research included the idea that the management of biobanks should actively promote public participation in biobank activities and popular acceptance of the collection and utilisation of biobank materials. Such a shift is not

only detectable in the discourse of ELSA expertise; it is also visible in the manner in which new national biobank initiatives were set up after the Iceland case, around the turn of the millennium. The case of the UK Biobank, in particular, demonstrates that the international community had learned many lessons from the Icelandic endeavour and, as a result, a strong ethical and governance framework was created before the launch of the biobank.^{43,44} Informed consent and privacy of the participants were again central issues in debates surrounding the UK Biobank. But even though the focus of the discussion was the protection of individual rights and privacy, this actually served to secure public trust in the UK Biobank, helping to solve the problem of attracting enough participants faced by all population-based biobanks.⁴⁵

National harmonisation and standardisation of legal and ethical procedures were also influential in ELSA discourse on transnational biobank networks. To identify best-practice models, scholars undertook comparative national case studies and legal analysis. In addition, international bodies like the HUGO Ethics Committee,⁴⁶ UNESCO,⁴⁷ the Council of Europe,⁴⁸ and the OECD⁴⁹ developed and published opinions and guidelines for biobank projects. Projects like P3G, PHGEN, PHOEBE, PRIVILEGED, BBMRI, and many others collected and archived the most relevant legal norms and guidelines on national and international levels and produced a battery of generic tools to be used in biobank administration and management to increase efficiency and harmonisation in collection, storage, and circulation of materials and information in biomedical research. Almost all these efforts built on the implicit or explicit association of biobanks with the public good. This equation assured a certain level of organisational certainty because of its promise of more stable financing and a willingness to donate genotype material and phenotype data.

While seeking “ethical frameworks that are sufficient to mediate between the competing interests at stake”,⁵⁰ scholars involved in the ‘communitarian turn’ argued that the bioethics community was trending towards approaches that emphasised the ideal of solidarity, as expressed by participation in research for the public good, instead of focusing on ‘mechanisms for obtaining informed consent and protecting confidentiality’. The concept of biobanks as global public goods was based on attempts to envision a movement of ‘genomic solidarity’, which would be nurtured by the promise that improved health lies at the end of the genomics rainbow. In the case of human genetic databases, so the argument went, constitutive solidarity would be at stake: individuals might perceive that they have an interest in common, namely better health care, and they might choose to get together to create a genetic database.⁵¹

The “Statement on Human Genomics Databases” by the HUGO Ethics Committee is an illuminating example of the second order discourse and its central arguments reappear in core academic contributions.⁵² It states:

Proposing that some of the principles and recommendations that follow may apply to both human and non-human genomic databases, The HUGO Ethics Committee adopts the following principles as a basis for its recommendations: 1) Human genomic databases are global public goods. 2) Individuals, families, communities,

commercial entities, institutions and governments should foster the public good.⁵³

Once the bioethical policy discourse incorporated this ‘public good’ approach toward biobanks, they were inclined to treat any act of resistance against them as an instance of a (manageable) ‘privacy problem’ on the part of individual donors. Within the discursive universe of second-order ELSA research, this followed almost logically: once biobank projects have become identified with the ‘public good’, everything that runs counter to them must hence be ‘bad’ from a public-interest perspective and can only legitimately be ‘good’ from a purely ‘private’ perspective – which, even if it has to be respected and valued to a certain degree in liberal societies, is not readily a legitimate basis for public policy. Fundamental disagreements about ideas and advantages of the public good, associated with biobanks, became therefore inconceivable. Attention could be directed to *protecting* donors or lay people from abuse and misuse of their data. However, ethical reflection increasingly concentrated on citizens’ sense of duty to promote research in the name of the public good.^{54, 55}

In a way, the idea of an altruistic ‘biological citizen’ was utilised in order to point out that people actually want to participate as donors in order to make genomic-based health research and drug development possible and more efficient. According to this line of thought, the motivation of individual citizens goes beyond their wanting to participate in biobank initiatives because it could benefit their own health; indeed, participation is viewed as an act of almost obligatory solidarity and responsibility. In a way, bioethics changed from an ethics for the life science research community to an ethics of citizens who have rights *and* responsibilities in relation to the biomedical research complex.^{56,57} Arranging sufficient protection of informational privacy, data protection, and an acceptable consent procedure in biobanks was seen as helping to achieve a satisfying donor participation rate. Such an arrangement would still respect personal autonomy, a leading principle of bioethics, by establishing a relationship resembling a contract between a donor and a biobank. The shift to this communitarian framework solidified the turn to a new order of ELSA expertise, which was committed to the promotion of biobanks and which envisaged its own role as the generation of the type of expertise that could help to manage problems such as data protection.

At the same time, it was recognised that informed consent often loses its ethical significance and becomes an empty procedure, because of the unspecified and uncertain uses of samples and information deposited in the biobanks. Consequently, the practice and even the notion of informed consent were called into question.⁵⁸ Many scholars of the second order connected their emphasis on biobanks as a public good with suggestions for open or broad consent.⁵⁹ The argument was that biobanks were able to serve as a public good only if they were able to use the material for future research towards new, currently unanticipated purposes.

One example of how the concerns identified by first-order discourse have been turned into regulative measures in the second order is the five-pillar concept proposed by the German Ethics Council.⁶⁰ It focused on protecting the interests of donors while

preparing the ground for massive biobank research expansion. Again, the main assumption was that a certain type of regulation must be created in order to maintain high participation rates for biobank projects that aim at promoting the public good.⁶¹

The five-pillar concept included a proposal for biobank secrecy, which would safeguard against third-party access to biobanks, whether by state agencies or by nongovernment parties such as insurance companies and employers. In addition, the ethics review committee of the biobank should preapprove all research projects that might use donors' personal data. But by way of reciprocation the proposal turned away from informed consent, because it seemingly conflicted with the freedom of science. The Council therefore argued for legislation that explicitly provides the possibility for giving broad consent.⁶² Once again, the assumption was that a combination of measures that protect personal data from third party intrusion on the one hand, together with expert decision-making bodies that take into account ethical and technical arguments on the other, would increase levels of public biobank acceptance.

However, in all these regulatory and ethical proposals privacy was treated as a *protective* means value. This means that it is assumed that "we value privacy because we could be harmed by the use or misuse of personal information about us".⁶³ But 'privacy' is an essentially contested and ambiguous term.⁶⁴ It is potentially loaded with heterogeneous motifs and interests that go beyond the wish to be adequately protected from the misuse of personal information.^{65, 66} In fact, most privacy conflicts are primarily struggles about the *boundaries* between the public and the private, and the significance of those boundaries.⁶⁷ People are not only worried about their personal privacy because they want to be protected. Often, they use claims to privacy in order to *demand certain levels of influence*. Active citizens are sometimes apprehensive about the goals and purposes of biobanks and demand that their voices are heard about the issue *how* the public good should be actively promoted.⁶⁸

The third order – recognising complexity and uncertainty through reflexivity

With the previous orders of ELSA research, many problems and concerns were identified, regulatory measures to control these issues were taken, and a fairly stable working environment for biobanks was created. These were important achievements, and we do not claim that the certainty it created will decrease in importance. Rather, our analysis of third-order ELSA research seeks to add elements that complement a drive for regulatory certainty. It points towards more inclusive mechanisms that promise to increase the quality and speed of organisational learning in biobank arrangements, which might be crucial in order to operate successfully under the conditions of knowledge-based societies.. Increasingly, however, economic fluctuations, political transformations, local controversies and changes in the attitudes about value of genomic knowledge are creating uncertainty. According to several authors, the pronouncement of sound regulatory solutions in the second order is not necessarily enough in this new context.^{69, 70} Biobanking as a practice is in constant development. So are its economic and cultural contexts. Until recently, for example, it was more or less assumed that the future of genomics was a bright one.

Groundbreaking scientific findings as well as commercial returns were and still are promised and expected. However, considerable doubts about such promises are appearing on the horizon.⁷¹ As a reaction, new approaches that deal with diverse viewpoints have been proposed.

Many scholars have already pointed to changes of emphasis and called for new approaches to evaluate and govern biobanks. Ursin, Hoeyer, and Skolbekken,⁷² for example, have analysed how informed consent in its various forms has been used strategically in the governance of biobanks. They were able to show how concentration on informed consent has geared discussion away from other concerns and from calls for ELSA research that goes beyond informed consent. In a similar way, Corrigan and Petersen⁷³ have demonstrated how problems associated with biobanks have been framed as risk issues for participants. In a further step, the regulation of these risks has been treated as the complement of the problem of securing large-enough participation rates. Regulation and 'ethical' governance structures have been designed so as to generate public trust. However, Corrigan and Petersen argue that public engagement and consultations designed to tackle this problem have not addressed the concerns of the public but have instead only served to legitimate biobank projects without questioning the promises on which their promotion actually rests.

There is an increasing amount of research that emphasises the idea that concerns about bioinformational privacy of potential donors in such projects should no longer be treated simply as calls for more and better protection of privacy from harm or misuse of these particular pieces of information. These questions about data protection and informed or broad consents emerged in correspondence with the second-order ELSA expertise. However, they are not necessarily congruent with the concerns about or demands for different types of care and new forms of distributional fairness^{74,75} that could be expressed in political spaces opened up by reflexive reasoning. Viewpoints on biobank issues are diverse and can encompass wider economic and societal issues – like the processes of scientific and economic utilisation of the information and samples they provided.^{76, 77, 78} They are part of a struggle for power and control in a policy area that is highly dependent on the ongoing investment of public money.⁷⁹

The new order of ELSA research that is emerging surpasses the public good/privacy dichotomy by acknowledging the ambiguity of peoples' motives and different contexts of participation. It examines ethical regulation beyond informed consent and data protection, and recognises the values (and limits) of different modes of public engagement. We propose that one function of this type of ELSA research is systematically to increase inner-organisational uncertainty and reflexivity in biobank projects by introducing different outsider perspectives into routine working procedures. This might appear paradoxical; yet, we argue that the purpose of this is to create new capacities for learning how to adapt to a not -controllable future through observing changes in the organised infrastructure's environment. This approach resembles some crucial elements of Dirk Baecker's sociological analysis of recent

shifts in management styles of other domains. The search for solutions for seemingly given or naturalised problems is replaced with the search for new questions and perspectives that enable the detection of chances and threats through distortions of routine organisational processes.⁸⁰ In this respect it is crucial to take into account that typical rule-based, bureaucratic organisations are social systems that routinely discourage learning. They are inflexible and therefore limit their interaction with their uncertain environment, by defining relatively narrow agendas and limited communications channels.^{81, 82} Rule following is more important than innovation, which opposes the premises of the contemporary programme of knowledge-based economies. Substantive rationality became increasingly replaced with reflexive rationality and more 'intelligent' organisations are able to adhere to the routines that are essential for their survival but hopefully 'naïve' enough to test whether the assumptions their routines rest on are still valid.⁸³

Similarly, the focus of many ELSA researchers has therefore shifted from generating regulatory answers (although this will remain important) to helping to create ways to test whether the assumptions that are built into a research system or infrastructure about its (social) environment are still valid. The ELSA scholars are questioning the functioning logics of biobanks – for example the idea that population biobanks should not return individual research results.⁸⁴ They are also becoming involved in co-developing and arguing for interactive settings of digital governance in which routine biobank settings and processes are approached from different angles and learning can occur.^{85, 86}

International networks of biobanks are regarded as needing new ways of thinking about governing biobanks. The given goal of generating a public good becomes even more difficult to define and has to be evaluated constantly, so 'public good' becomes explicitly (re-)defined in this process.⁸⁷ The third order ELSA research emphasises communicative processes that bring different perspectives, opinions, and interests to the table in order to serve as common problems that unite actors and stakeholders. This procedural rationality is very much the essence of governance processes.⁸⁸ In this sense, problems (like privacy contestations) are becoming resources for governance processes that must solve how to bring together a heterogeneous set of actors around a common policy task. An ethics of conviction, which assumes a given hierarchy of values, becomes increasingly complemented with an ethics of responsibility that assumes that a value conflict is the context of every moral endeavour and no hierarchy of values can be stipulated. Governance is therefore no longer understood only as a means to solve conflicts, but rather as a set of attempts to manage them in innovative ways and critically understand and assess identified problems and concerns.⁸⁹

Instead of assuming that biobanks are public goods *per se*, more and deeper analysis about the circumstances in which biobanks are treated as public goods is needed. The public good/private concerns conceptual framework offered by communitarian ethics is not suited to answering these questions in an empirical fashion.⁹⁰ Working on this task means acknowledging, facing, accepting, coping with, and even embracing uncertainty in order to increase communication and connectivity. Therefore, third-

order ELSA research can turn the explicitly strategic assumption of the communitarian turn in ethics into strategic questions that can be systematically reactualised from time to time: Is this specific type and practice of biobanking considered to be for a public good? By whom? What motives are presented? In what ways do perspectives of internal observers differ from perspectives that are held outside of the core biobank organisations? In short, the emphasis is shifted to the different ways in which stakeholders negotiate and define the public or common good.

The social science literature as well as political practice has developed a substantive toolbox for participatory arrangements with different publics, including traditional opinion polls, focus groups, citizen juries, and scenario workshops.⁹¹ Although many of these engagement processes have served as legitimating tools that have not really been incorporated into the actual decision-making process, each of these governance instruments potentially creates a different but limited perspective of what it means to be a citizen or a political subject. Likewise, the third-order ELSA expertise can offer solutions to integrate engagements in manners useful to biobank insiders as well as to outside stakeholders. Useful models of how this must be done in the field of biobanking can be found, for example, in the activism of patient groups and networks,^{92,93} but the greater challenge might be including more diverse groups and their views about political and socioeconomic topics such as the usefulness of biobanks, the effects of internationalisation, and the commercialisation of research.⁹⁴

In addition, reconsidering biobank governance from a procedural aspect, which aims at multiway communication between a potentially infinite constituency, throughout the life cycle of biobanks would also address the problem of blind responsibility that is created by the altruistic genomic solidarity reasoning, where donors are expected to take responsibility for the public good by participating in biobank efforts without knowing their consequences.⁹⁵ When future uses and institutional configurations of biobanks are not known to donors (as is acknowledged), they are bearing responsibilities for issues beyond their control. Implementing transparency and procedural communicative arrangements lessens this blind responsibility and creates actual co-responsibility for delivering common goods.^{96,97} Clearly, it is not the duty of the involved publics to manage and govern everything that happens in biobanks. Therefore, it is crucial to reflect donors' expressed motives, interests, and concerns onto the biobanking practitioners and their everyday work, where for example categories and conceptions about race and diseases are still being produced in manifold ways.⁹⁸ ELSA expertise can mediate such complicated social relations between biobanking organisations and a society that is becoming ever more heterogeneous and complex. The task is delicate since it has to be delivered without being prone to the categorical oversimplifications that seem to offer easy ways out of political, moral, and ethical conflicts.

Conclusions

Biobanks assemble large numbers of people, organisations, and technical procedures. This implies multiple expectations, concerns, and opinions about how to collect, store, circulate, and deploy tissue samples and molecular and health information in a

justifiable manner. ELSA experts have debated, for example, how to attract tissue donors, how to secure public trust, and what proper legal and ethical regulations are.

We have identified three orders of ELSA expertise on biobanks that have addressed the problems related to biobanking and suggested ethically and socially acceptable procedures for collection and distribution of biobank material. The first-order ELSA expertise was mainly critical in tone and approached problems of biobanking through protection of the donors' privacy and rights in circumstances where there was regulatory uncertainty about the operation requirements of biobanks. The second-order ELSA expertise introduced regulatory solutions to many ethical, legal, and social concerns by the development of national regulation and international harmonisation. The idea of biobanks as producers of a public good became a central notion in securing sufficient participation rates to biobanks.

We have suggested that a third order of ELSA biobank research that builds on these previous achievements is emerging. This order seeks to promote learning processes and critical reflexivity. It aims at challenging some of the basic assumptions that have guided the academic policy proposals and problem identification processes of earlier orders - like the public good/privacy framework - and identifies places for new communications and procedural strategies. In that way it offers the biobank community new concepts, methods, and insights from perspectives that help to adapt to an uncertain and essentially underdetermined future by reintroducing uncertainty into already regulated and stabilised organisations.

During the past years, the focus of setting up and running biobanks has changed from national sample and information collections to complex transnational organisation of biobank infrastructures and international circulation of biomaterial and information. Transnational networks that aim to circulate bioinformation with growing efficiency operate in an increasingly complex environment filled with uncertainties. On one hand, samples and information are collected in local settings where large numbers of stakeholders have differing views on risks and expectations about the results and goals of biobanks. On the other hand, research and development are conducted in global contexts with another set of stakeholders. The task of third-order ELSA expertise under these circumstances is to help in identifying the needs of different stakeholders and to introduce reflexivity throughout these processes by questioning and evaluating existing practices.

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