Being a member of the club: the transnational (self-) governance of networks of biobanks

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Abstract: Biobanks have become one of the core resources for biomedical research. At the same time, a number of risks associated with processing and storing of biological material and corresponding data have been diagnosed. This paper focuses on how institutionalised transnational networks of biobanks generate practical answers to some of these risks. Drawing upon three case studies – GenomEUtwin, EuroBioBank and P3G – we illustrate how soft law (such as guidelines and best practice protocols) emerges as a by-product of the standardising activities undertaken to enable and facilitate transnational research collaboration – which in times of genome-wide association studies has become as important as never before. As our case studies show, the creation of ethical standards, as well as adherence to them, in the context of networks of biobanks is neither imposed on the scientific communities, nor is it separable from the very core of scientific research; instead, ethics and science are literally co-produced.

Keywords: biobanks; genomics; risk; transnational collaboration; practice; ethics; governance.

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1 Introduction: biobanks, genomics, and the network concept

Biobanks, broadly defined as combinations of biological material and personal data of the patient/donor for diagnostic, therapeutic or research purposes, gained importance as crucial tools for biomedical research during the so-called '(Post-) Genomic Era'[1]. Generally, biobanks are not a new phenomenon; biological material has been collected for various purposes since the beginning of modern medicine (Cambon-Thomsen, 2004; Hansson and Levin, 2003). Biomedical research has a long tradition of handling and managing bodily material both for research as well as diagnostic and therapeutic purposes (Strasser, 2006; Lindberg, 2003; Hirtzlin et al., 2003; Holm and Bennett, 2001; Hilgartner, 1995). Yet, in the last two decades, biobanks have obtained new significance insofar as the organised large-scale collection of human DNA and tissue samples in connection with the facilities of computerisation of personal data poses new ethical, legal, social and political challenges and risks, such as adequate protection of privacy rights. The management of perceived risks related to biobank projects has been addressed in several legal documents and academic publications; most of these address issues such as data protection, ownership and commercialisation (Maschke, 2005; Knoppers, 2005; Chadwick and Wilson, 2004; Austin et al., 2003), informed consent (Wright-Clayton, 2005; Hoeyer et al., 2004), as well as bioethical issues on a more theoretical level (Knoppers and Chadwick, 2005; Knoppers, 2003; Salter and Jones, 2002; Andorno, 2002). Frequently, authors refer to the problems encountered by the Icelandic Health Sector Database project (Pálsson, 2007; Rose, 2006; Cutter and Wilson, 2004); arguing that the success of a biobank depends on reflexive risk management by means of public participation/consultation models (Gottweis and Petersen, 2008). While there is a plethora of scholarly discussions about the risks inherent in large-scale biobank projects, this paper argues that many tools for risk-governance emerge out of the very practices of 'biobanking' itself (such as running and managing a biobank). Based on the analysis of three networks of biobanks we will argue that in the context of transnational research and research management collaboration, the coordination and harmonisation of scientific standards (such as the description of phenotypic information, but also stem cell lines) often generates ethical guidelines and best practice protocols as a 'by-product'. Put differently, harmonised scientific standards and ethics are being co-produced (Jasanoff, 2004).

Before we start with our analysis, we will briefly outline the context in which biobanks are situated in the 21st century. As mentioned earlier, biobanks emerged as resources for genetic and genomic research. Genomics is concerned with the sequence,

function and interaction of genes. However, what Adam Hedgecoe said about the use of the term 'pharmacogenomics' might be true for the field of 'genomics' in general: it signifies 'more than just technological advance' [Hedgecoe, (2003), p.514]. This is not to claim that genomics is merely an 'invention' of scientists and policy makers to obtain research money; rather, what it is meant to say is that the emergence of genomics signifies a larger shift than just new scientific breakthroughs and advances in knowledge. Genomics implies new ways of knowledge production, including its conditions, and new modes of applications and implications. This becomes apparent if we take into consideration a dimension which is one of the constitutive factors for the entire field: the dimension of transnational networks.

The symbolic starting point of the Genomic Era, the Human Genome Project (HGP), was characterised by the collaboration of public research institutions and commercial companies in a way that transcended nation states and shifted the self-understanding of science. Whereas at the early times of biotechnology, cooperations between the public and the private sector 'were for the most part unofficial and considered dangerous for the functioning of science' [Shorett et al., (2003), p.123], corporate interest in a field of research has become a facilitating factor for receiving public grants. Collaborations between pharmaceutical companies and academic research laboratories have become the norm, across national borders.

In addition, the Genomic Era is also characterised by a complex interrelationship between scientific, ethical, social, economic, informational and political formations at different levels of governance. Thacker's (2004) notion of 'biomedia' captures that particular assemblage of biology, technology and politics (see also Ratto and Beaulieu, 2006); the biological component is inseparably intertwined with it from the start. Beaulieu sees 'the development of novel, networked databases replete with data consisting of digitised biological information from multiple sources […] as part of the 'informational turn' in biology' [quoted from Ratto, (2006), p.31; see also Beaulieu, 2004].

In this context, it is hardly surprising that biobanks are not only the result of networked activities of life scientists, but they are also frequently organised as networks of biobanks. These are interconnected groups of actors which mainly consist of biobanks, including both their material (human and other natural as well as technological) and immaterial (knowledge and other intellectual property) representations, as well as other individuals or institutions in the field of the life sciences (such as IT companies, patient organisations or ELSI/ELSA experts). Already existing informal network practices of researchers co-determine the design and the daily practices of formally established networks (such as in the case of a research funding application). The institutional design of networks of biobanks can be misleading because the 'real' network (understood as the group of actors who set research agendas and actually collaborate in the process of knowledge production) can include individuals or institutions who are not official or full members of the formal network. Similarly, the list of members of the official network can be misleading as the actual importance of some official members might be very small compared to others, and because the structure of the European commission's framework programmes (FPs) are known to foster strategic grouping (for example, members from new accession countries and/or from Southern Europe are taken on board to 'please' referees and funding agencies). This, however, does not mean that the official network structure is unimportant. On the contrary, the official and institutionalised network structure creates a variety of by-products to the mere fulfilment of research objectives.

For example, the process of agreeing upon 'best practice' protocols and harmonising practices with regard to collecting and storing samples, practices of shipping, and practices of obtaining informed consent, are often 'collateral' outcomes of transnational networks of biobanks which not only facilitate research collaboration in the present but also make it more likely that members collaborate closely in the future (as infrastructures have already been established and many practices have been harmonised or at least rendered compatible).

Another 'unintended consequence' of transnational networks of biobanks is the active contribution to what can be called the global bioethics complex (Salter and Jones, 2005). The joint work on protocols and practice agreements within a network homogenises practices throughout the network and spreads it beyond the network's borders, which accelerates a further transnationalisation of both shared knowledge and shared practices. Thus, as many (networks of) biobanks are just yet beginning to have firmly established sites, practices, modes of governance, operation and supervision, or risk assessment and management at the time they are being set up, the process of developing the right 'tools' is often as much part of the project as the working towards the scientific research objectives for which the tools are developed. UK biobank (http://www.ukbiobank.ac.uk/), whose establishment has been accompanied with an extensive public consultation process since long before it became operational, is an illustrative example. Despite it being a national project rather than a transnational network, the negotiation of scientific objectives and ethical safeguards was a transnational endeavour and relied on, to a large extent, the experience of other countries and the expertise of international experts (Barbour, 2003; Tutton et al., 2004; Petersen, 2005).

Due to the lack of competence or reluctance of important political entities such as the European Union (EU) to get involved in the potentially sensitive activity of regulating biobanking, the field is characterised by a large number of non-binding regulations, 'soft' rules of bioethics, and 'soft' modes of governance which manifest themselves in practices of self-regulation and self-monitoring to govern associated risks. Put differently, in the context of transnational research collaboration, enforcing ethical conduct in processing and using samples and data from biobanks is neither imposed on the scientific communities, nor is it separable from the very core of scientific research; instead, it enables transnational collaboration by harmonising, if not standardising the ethical and scientific quality of research objects and subjects. Ethics and science, in this sense, are literally co-produced.

In what follows, we will first give a brief overview of transnational biobank regulation. In doing so, we aim to show that systematic and explicit legislation on biobanks is absent both at the European and at the international level. We will argue that modes of self-regulation have become a practical condition for both scientific success and public acceptance of (networks of) biobank projects. Best practice protocols, charters, etc, have become just as important as legal guidelines (if not more important). Secondly, we will examine the programmatic and institutional design of three networks of biobanks, namely EuroBioBank, the Genome-wide analyses of European twin and population cohorts to identify genes predisposing to common diseases (GenomEUtwin), and the public population project in genomics (P3G). Particular attention will be paid to the actual practices of members of the networks. The central part of the paper will consist of the analysis of about twenty qualitative interviews conducted with policy makers,

biobank managers, and biobank employees about practices of transnational research cooperation.

2 Transnational biobank regulation: European and international level

2.1 Explicit legislation and regulatory approaches to governing biobanks

Over the last years, various players on the international and transnational level have produced several reports, documents, recommendations, etc addressing the legal and ethical challenges that have been raised by the emergence or reevaluation of biobank projects. Systematic and explicit legislation on biobanks, however, is neither present at the European nor at the international level. Especially the reality of networking among biobanks seems to be far ahead of all regulative attempts.

First and foremost, the United Nations (UN), the Human Genome Organisation (HUGO), and the Nuffield Council on Bioethics[2] are important players at the international level, addressing ethical and legal issues arising in the context of biobanking. Another important player at the international level is the Organisation for Economic Cooperation and Development (OECD) which has established two working groups dealing with human genetic research databases (cf. OECD, 2006) and biological resource centres (cf. OECD, 2007a; OECD, 2007b; OECD, 2001) respectively.

At the European (non-EU) level, the most important organisation with regard to biobanking activities is the Council of Europe (COE). It has produced a number of documents relevant for biobanking activities, most recently the Recommendation REC(2006)4 of the Committee of Ministers to Member States on Research on Biological Materials of Human Origin together with an Explanatory Memorandum providing guidelines for biobanks. Among the COE's documents and recommendations, we consider the European Convention on Human Rights and Biomedicine of 1997 (or Oviedo Convention) to be the most important one[3]. For countries which have ratified it, the convention is legally binding.

At the EU level, several legal documents are relevant for biobanks. Among them we would like to point out the Directive 95/46/EC on the Protection of Personal Data; the Directive 98/79/EC on In Vitro Diagnostic Devices; the Directive 2001/20/EC on Clinical Trials; the Directive 2004/23/EC on Setting Standards of Quality and Safety for the Donation, Procurement, Testing, Processing, Preservation, Storage and Distribution of Human Tissues and Cells; and the Directive 2006/17/EC implementing the Directive 2004/23/EC of the European Parliament and of the Council as Regards Certain Technical Requirements for the Donation, Procurement and Testing of Human Tissues and Cells. On 31st May 2007, following the opinion of the European Parliament on 25 April, the Council of Ministers approved a Regulation on Advanced Therapies, emanating from the work of the Enterprise and Industry Directorate-General on regulating cell therapies, gene therapies and human tissue engineered products[4].

Most of these documents do not contain the terms biobank or biobanking; they do, however, pertain to core activities of biobanking such as the processing of personal information, the use of human biological material, and some of the prerequisites for research involving humans, such as the protection of personal data. The EU itself, due to the 'Subsidiarity Principle'[5], has no authority to issue legislation or regulations on the topic of biobanks (health matters still lie in the competence of member countries).

However, European community (EC) regulations governing the internal market, trade, and competition, have an impact on national health policies, such as the principles of the free movements of goods and services, which apply also to the provision of medical services and the import and export of human substances and medical goods (see Hämäläinen et al., 2004; Philipson, 2001)[6].

In addition, of course, the EU represents an important funding agency for biomedical research. The design of its research funding structure, as we will show below, has immediate effects on the kinds of official networks of biobanks that emerge. EU institutions also regard themselves, to some extent, as guardians for ethical standards with regard to the establishment and administration of biobanks and related activities[7]. Although the EU itself lacks a mandate to bind biobanks by ethical rules, several Directives issued by the Council of Ministers address ethical aspects, such as the Directive 98/44/EC on the Legal Protection of Biotechnological Inventions, or the Directive 2004/23/EC on Human Biological Materials. Moreover, the European Commission established the European Group on Ethics in Science and New Technologies (GAEIB, mandate 1991–1997) and the European Group on Ethics in Science and New Technologies (EGE, consecutive mandates since 1998), which already provided opinions on human tissue banking and related issues[8]. Another important way to 'implement ethics', therefore, are the FPs through which several biobank projects are (co-)funded. A former employee of the European Commission explained:

> "The Commission does not really have any mandate in relation to ethics anyway, except […] the FP and the rules of the FP. […] but in terms of the EU Commission they are not able to tell a particular member state what it has to do in regards to ethics. [...] So you really can't say, well, let's harmonise what we're doing. That's not really something that's within the Commission's doing [...] because the ethical rules of FP6 and also the Seventh probably, I suspect, say that any research has to comply with ethical rules of FP6, and one of the ethical rules of FP6 is that all European directives must apply. So even if you do research in China, for example, the research is there, you still have to comply with ethical, with FP6 ethical rules." (Interview P, Research Directorate-General, 2005)[9].

Already under FP5 (1998–2002) issues of bioethics regulation had been addressed. This debate continued within FP6 (2002–2006), and continues to do so during FP7 (2007–2013). FP7 reconfirms the ethical principles of the previous FPs and explicitly excludes the same research areas, such as the creation of human embryos solely for research purposes, from EC funding.

A novel and innovative form to 'implement ethics' alongside FP7 came about with the creation of the European strategy forum on research infrastructures (ESFRI). ESFRI brings together representatives of EU member states and associated states (both appointed by their national governments) and one representative of the European Commission. Its mandate is to identify new strategies and to develop a roadmap for the creation of research infrastructures[10]. One brainchild of ESFRI seeks to establish a pan-European Biobanking and Biomolecular Resources Research Infrastructure (BBMRI)[11] and has recently responded to a non-competitive call of the European Commission for such infrastructure-building proposals[12]. In other words, the co-production of ethics and science already begins at the stage of proposal writing. The focus on building sustainable research infrastructures, rather than short-term research collaborations, is seen to be necessary in times in which cost-intensive collaborations

whose future funding is unclear pose a considerable risk to participating institutions. Long-term solutions are very much needed.

2.2 Soft rules of bioethics, and the globalisation of morality

In the Genomic Era, technological advance progresses much faster than governmental regulation is able to progress. This partly explains why 'voluntary' adherence to ethical guidelines has become virtually as important as obedience to law and explicit regulation. It is not very hard to imagine what would be the outcome of a scientific publication drawing upon DNA samples or other bodily materials for which the procedure of obtaining the donors' informed consent was flawed (some of us will have no trouble coming up with a number of examples). Furthermore, it has become virtually impossible to use samples whose 'ethical' origin is dubious. The scandal around the cloning fraud of South Korea's former science hero Woo-suk Hwang is a telling example of this trend (Gottweis and Triendl, 2006; Annas, 2006). What Salter and Jones (2005, p.717) argued in their analysis of the emergence of UK Biobank is true for almost any biobank which is currently operating: 'The bioethical discourse is elevated to the status of a sine qua non of the biobank project'; even more so for transnational biobank networks, which exceed the competence of national regulatory competences. 'Bioethics', as Brian Salter and Mavis Jones continue, 'may not be a united epistemic community but it is undoubtedly an influential transnational policy network capable of working easily across the political spaces of multi-level governance...' [Salter and Jones (2005), p.725, See also Salter and Jones, 2002; Reinicke, 2000; Coleman and Perl, 1999].

In this respect, the 'soft' rules of bioethics and the protocols and agreements arising in this spirit still differ in relevant aspects from the common understanding of 'soft law' even when they are not enforced by state authorities. Referring to the approach endorsed by Dehousse and Weiler (1991) and Cini (2001, p.195) describes soft law as 'symbolic policy, marking out a certain common direction without formal commitment'. This view, however, implies a 'top-down' perspective, assuming the point of view of centralised national and/or supranational governmental agencies who attempt to govern societies most effectively without running into major points of resistance (which might occur in case of binding laws). What this understanding leaves out of the equation is that addressees of such policies often have a vital interest in articulating a 'formal commitment' to these 'soft' standards (note that neither should 'soft' be conflated with 'fuzzy' nor 'unconcrete').

In the case of the transnational and global governance of biobanks (and networks of biobanks), non-legally binding agreements and 'soft law' regularly emerge in the absence of a central (European, or 'global') regulator. They stem from the practitioners' need for mutual agreements, protocols and guidelines to safeguard them against accusations of flawed ethics. This can be seen as a pragmatic way of self-governance from the side of biobankers for the sake of both their scientific objectives and the reputation of their careers and institutions.

3 Networks of biobanks

In this section, we will focus on the programmatic and institutional design of networks of biobanks in a comparative manner. Particular attention will be paid to the actual practices

of members of the networks, which we explored through the study of the networks' websites, ethnographic research, and semi-structured qualitative interviews[13] with key actors (cf. Liamputtong and Ezzy, 2005; Ezzy, 2002; Weiss, 1995)[14]. The following analysis draws upon three cases of networks of biobanks: EuroBioBank, GenomEUtwin, and P3G.

The EuroBioBank network currently comprises 12 academic or private biobanks from seven EU countries, a biobanking consultant, and the alliance of patient organisations European Organisation for Rare Diseases (Eurordis) who initiated and has coordinated the network ever since it was established. Initially, the project was financed by the EU under FP5 (2003–2006). From then until today, EuroBioBank's main objective has been to 'optimise the use of existing collections and encourage the creation of new ones' by fostering 'collaborations in the medical and scientific community and stimulate research in the field of rare diseases'[15]. To ensure the sustainability of the network after the end of the EU-funded period in 2006, EuroBioBank was supported by two grants from the German Association for Patients with Muscle Disorders (DGM[16]) and the French Association Against Myopathies (AFM[17]); it also received funding from a corporate sponsor, PromoCell[18]. Additionally, it levied a membership fee for the continuation of its activities until further funding was obtained in 2007, when Eurordis became a partner and leader of the work package on biobanks in the TREAT-NMD project: translational research in Europe assessment and treatment of neuromuscular diseases. The European network of excellence, funded by the FP6, aims to accelerate the development of treatments for neuromuscular diseases.

The GenomEUtwin project is comprised of several population cohorts, including Danish, Finnish, Italian, UK, Dutch, Norwegian, and Swedish twin cohorts as well as the MORGAM epidemiological cohorts. Furthermore, GenomEUtwin is a founding member of P3G. Its initial main objective was to 'capitalise special advantages of Europe in population genetics by efficient collaboration of twin researchers, genetic epidemiologists, molecular geneticists and mathematicians'[19]. It also includes Australia's genetic epidemiology group as an associated partner. All GenomEUtwin partners represent particular areas of expertise and platforms. Between 2002–2006, the network was financed by the FP5. Today, the network receives no more official funding but scientists continue to collaborate on joint publications and seek to secure funding to maintain and/or expand the existing network (interview M, GenomEUtwin, 2007). Furthermore, several projects have built upon the platforms developed under GenomEUtwin.

P3G was launched by the three founding partners CARTaGENE (Canada, Quebec), the Estonian Genome project (Estonia), and GenomEUtwin. As of today, it consists of 19 charter members[20]. Its goal is to promote collaboration between researchers in the field of population genomics in order to establish a free and open knowledge-database. Since its initiation, P3G is sponsored by Genome Quebec[21] and Genome Canada[22]. Additionally, it levies a one-time membership fee.

3.1 Why networks?

Historically, EuroBioBank is the brainchild of the French patient organisation AFM, which, together with Eurordis, developed the concept of EuroBioBank. They identified research on rare diseases as a disadvantaged field because of both the lack of high quality

human DNA, cell and tissue samples of rare disease patients, the little interest of researchers in rare diseases and the very limited financial investment. In overcoming the problem of the small number of human biological samples available of rare disease patients, they hoped to 'reach a critical mass of collections and accelerate research on rare diseases'[23]. This endeavour seemed most promising in a network structure, drawing on both the expertise of existing biobanks and already available sample collections finally made more visible. EuroBioBank regards itself as an informational nodal point which enables and accelerates coordinated research (interview H, EuroBioBank, 2006).

The GenomEUtwin network emerged out of a tightly knit group of twin researchers, an informal network that had existed prior to the emergence of the formal GenomEUtwin structure. The network was organised around the conviction that twins 'are the best designs in genetic epidemiology' (interview E, GenomEUtwin, 2006). As stated at the GenomEUtwin website, the general research objectives are:

1 'to develop (an) intellectual European framework to stimulate inventions and novel strategies to utilise maximally the unique features of population cohorts'

2 'to utilise the synergy between twin cohorts and population cohorts in studies of genetic and life style predictors'

3 'to create unique infrastructure for research into common diseases and the training of scientists in quantitative biology'.[24]

The story of P3G is that an international group of researchers concluded that the time was ripe for an internationally concerted approach to deal with the challenges of biobanking activities, in order to prevent parallel discussions leading to different agreements and standards. All our interviewees emphasised the importance and urgency of transnational collaboration, as much is at stake in the expanding landscape of biobanks across the globe:

> "We never had these huge biobanks before. This is all a new field. […] So if you are opening a project like UK Biobank and it is a £ 90 million project, you can't miss (out). It has to be done the right way the first time. […] if you want this, this population based biobank to be able to collaborate with other ones, to be able ... to validate... to cross-validate your results, you have to think about it now. It's gonna be too late in ten years." (Interview B, P3G, 2006).

In a nutshell, all three networks of biobanks discussed in this paper aim to learn and benefit from already existing knowledge, expertise and/or sample collections through transnational collaboration. In the words of one interviewee, networking and transnational collaboration are grounded in the common understanding that there 'is no need to reinvent the wheel' (interview C, GenomEUtwin, 2005). Also, our interviewees regard the possibility to participate in such a network as a small window of opportunity which requires rapid action.

3.2 Membership, access, and network design

Initially, EuroBioBank consisted of a limited group of members and was divided up into eight work packages (e.g. work package on technical and quality issues for DNA including corresponding standard operating procedures (SOPs)). Today, EuroBioBank is open to new members. All members, new and old, have to commit themselves to comply with the principles defined in a charter governing the network since 2006. A website

offers intranet access for members. Additionally, the website contains information for both the general public as well as researchers, which enables them to access, for example, the online-catalogue of accessible human DNA, cell and tissue sample collections on rare diseases[25].

GenomEUtwin comprises of members representing particular areas of expertise and platforms but do not necessarily have cohort data. The project was built around the five intellectual cores; genotyping, epidemiology, database, statistics and ethics[26]. While financed by FP5, only membership granted access to the data, samples and expertise. Using a metaphor used by one of its members, GenomEUtwin has been an exclusive 'club' where one could get a piece of the cake only if one managed to get a seat at the table (interview E, GenomEUtwin, 2006). A look at the website supports the notion of a closed 'club' because it provides only basic information about the network accessible to the general public, without any details on actual collaborations between network members. Until today, GenomEUtwin's official network design remains determined by the initial grant proposal. However, the official list of members fails to mention the Australian participant who in practice plays an important role in the network. Despite the fact that they were not Europeans, they were included as an associated member because 'they represent so much expertise, and also have so many valuable samples that... it would have been foolish not to include them' (interview D, GenomEUtwin, 2006).

P3G has an open membership policy. It is comprised of three categories of members, namely charter members, associate members and individual members. P3G focuses on population biobanks but is not limited to these. Its activities are not linked to a specific research goal. P3G was created on a supposedly neutral meta-level, networking above the national interests of particular countries or research teams in a 'non-competitive' (interview B and O, P3G, 2006) manner. In the diction of one of our interviewees, P3G appears as an 'international organisation' (interview O, P3G, 2006) for voluntary self-regulation, harmonisation and standardisation. General information about P3G is accessible at the website, where, for example, the reports and presentations of former meetings can be downloaded. Besides general information about the mission and structure of P3G, the website provides a link to the so-called 'P3G Observatory' which is its 'knowledge transfer platform'[27], providing access to the works of the P3G Cores and Working Groups, etc. It was emphasised several times in our interviews that P3G has an 'open approach' (interview B and O, P3G, 2006) towards networking, which probably means that the objective is to 'create common tools' (interview B, P3G, 2006) without interfering in the individual domains of its members. We suppose that it also indicates that the network is not shaped by restrictions or requirements by its sponsor but is rather formed by self-regulatory practices which emerge out of the self defined needs of the network members: collaboration is taking place where members want it to happen. In contrast to GenomEUtwin and EuroBioBank, neither data nor samples are shared in the context of P3G. The only resource shared is experience and expertise on how to deal with the scientific, ethical and legal challenges of biobanking.

3.3 Transnational cooperation and interaction of players: the co-production of scientific standards and ethics

According to our interviewees, ethical considerations are an integral part of any kind of biobanking practice. In relation to SOPs, for instance, ethical rules can be understood as

one component of the network's quality standards (interview J, EuroBioBank, 2007). Necessarily, ethical norms 'oblige us to do much more work (they are particularly time consuming, eds.)' (interview Q, P3G, 2007), but they are 'an inseparable part of our scientific endeavour' (interview K, EuroBioBank, 2007). In other words, the production of ethical norms is inseparably intertwined with standardisation and harmonisations activities which form a core part of every network.

In the case of EuroBioBank, for example, the ethical principles guiding the activities in the network were established by the EuroBioBank Assembly. One manifestation is the network's informed consent form, which is the product of several discussions among network members and expert consultations. The informed consent form now serves as a basic template for the activities of all network members; paragraphs may be added if required by particular national provisions, but nothing must be dropped. This mechanism is a good example for the co-production of science and ethics: The process of agreeing on a common form is guided by the conviction that it will facilitate transnational sample and/or data exchange, which in turn will often facilitate more interesting and valid (due to larger number of samples available) research outcomes. As the next quote demonstrates, the way in which the scope of many research projects is conceived has shifted from the national to the transnational level. This does not mean that national regulatory and cultural particularities disappear, but rather that they become an object of explicit strategic consideration. When asked what has changed for them, on the practical level, since the formal creation of GenomEUtwin, one of our interviewees stated:

> "Many of the registries have been collaborating previously but now we have a database standard and we have a very strong ethics core that is helping us with guidelines and what's different across countries and what's similar across countries." (interview D, GenomEUtwin, 2006).

As our interviewee indicates, an important output of the official network structure is 'a better guideline for collaboration and transfer of data and transfer of materials' (interview D, GenomEUtwin, 2006) and therefore also an accelerated harmonisation of various aspects of the handling of bodily material and data in biobanks. These guidelines are products of the network's working groups (the 'intellectual core facilities') and draw upon already existing knowledge on certain matters.

Practically, agreements were reached by 'all combinations of communications' (interview D, GenomEUtwin, 2006), including face-to-face meetings, video-conferences, email exchange and phone calls. In addition, GenomEUtwin partners frequently held meetings, exchange conference calls, and co-produce papers according to a decided publication strategy. Additionally, academic exchange has had a large effect on the harmonisation of practices, which is frequently described in terms of 'mutual learning': Without the creation of GenomEUtwin, one of its members explained, 'I would not have learned as much about different kinds of linkage studies and different formats of the kind of studies we're doing' (interview D, GenomEUtwin, 2006). In practical terms, scientific protocols and ethical codes 'came along where they were needed' (interview E, GenomEUtwin, 2006).

In the case of P3G, our interviewees admitted to find it difficult to explain the nature of the organisation. Throughout one interview, it was pointed out several times that representatives of biobanks (P3G's potential and actual members) are frequently suspicious about P3G at first, as they suspect them 'taking over' with the purpose of 'trying to create *the* biobank' (interview R, P3G, 2006, interviewee's emphasis). In other

words, P3G is a network of biobanks but is not a biobank itself, as it neither collects nor exchanges biological material and personal data but solely facilitates the creation and exchange of expertise related to transnational research management, ethics, and regulation. As one of our interviewees explains:

> "P3G is not about going to tell people who are members how they should conduct their research. […] I mean, they keep their own code, their own governance on their project, but they come to our meeting and they learn from the experience of others that try to set up a same thing […]." (interview B, P3G, 2006).

Instead of a list of deliverables in the project proposal, topics of discussion are set on the agenda of the international working group consists of several smaller units, the so-called 'P3G Cores'[28], which focus on specific topics such as integrating data or validating new technologies for biochemical analyses or genotyping.

In relation to the P3G ethics core, both bioethics experts and biobank managers work together addressing emerging issues on, for instance, confidentiality or data security. The work is strongly guided by the conviction, as one of our interviewees has phrased it, 'that we all share the same DNA after all' (interview Q, P3G, 2006), and that this obliges to not only secure but global standards for data exchange:

> "In the end, everything comes down to ethics for us. You cannot bypass it and we just do not know what to do... It is just part of our work ... We have people from Scandinavia. We know their code of conduct, but what about people from Poland? Can we give them our samples? I do not know Polish, I do not know how they do things there..." (interview S, P3G, 2006).

In other words, the harmonisation of ethical standards and practices across border is seen as a condition for successful transnational collaboration. 'With a biobank from a different country, we want to be able to assure the participants (the donors) that the ethical standards are as high as ours' (interview Q, P3G, 2006).

In comparison to EuroBioBank and GenomEUtwin, the 'outcomes' of P3G are not 'specific results' applicable to a single (network of) biobank(s), but rather general guidelines for voluntary self-regulation, harmonisation and possibly standardisation.

4 Conclusions

In the Genomic Era, the organised collection of human biological material and data has gained a new significance and poses new ethical, legal, social and political questions. The practice of biobanking, formerly a side-activity of clinical or research activities, is today on its way to become a profession of its own right, with its own ethical standards and modes of governance. While biological material is increasingly seen as crucial resource for biomedical research, a wide range of risks, such as infringement of genetic privacy and of data protection, associated with the processing, storing and exchanging of material and data, has been diagnosed and discussed. Frequently, this has interfered with the planned establishment and use of biobanks, such as in the cases of Iceland and the UK.

This paper argues that networks of biobanks provide an example of inclusive risk governance emerging out of the field itself: by discussing three networks of biobanks (namely EuroBioBank, GenomEUtwin, and P3G) we have shown that 'soft law' pertaining to ethics emerges as a by-product of the harmonising and standardising

activities, which are integral parts of enabling and facilitating scientific collaboration across borders.

In the case of GenomEUtwin, the standardisation of data, for instance, is understood as a necessity for ensuring the validity of common research endeavours and resulting publications. Here, the notion of standardisation does not only refer to the technical dimension of biomedical procedures, but also to the ethical dimension: was the material obtained in compliance with ethical standards? The complex interrelationship between scientific and ethical formations can be exemplified also with our data on EuroBioBank. Here, one of our interviewees highlighted that 'ethically sound' material and data is a quality dimension of the network of biobanks. Additionally, if research is more ethical, it enables cooperation. Put differently, in the context of transnational research collaboration, enforcing ethical conduct in processing and using samples and data from biobanks is neither imposed on the scientific communities, nor is it separable from the very core of scientific research; instead, it enables transnational collaboration by harmonising/standardising the ethical and scientific quality of research objects and subjects. Ethics and science, in this sense, are quite literally co-produced.

Currently, the EU is moving in the direction of supporting networks to an even larger extent than it has been the case in the past. Even the responsibility for administrating and distributing the funding money is being delegated into the research networks themselves. The idea, however, that the objective 'to connect Europe' [Jan-Eric Litton[29] quoted from Ratto (2006), p.43] is very high on the list of priorities of network members is to be contested. Their actions seem more guided by the will to overcome specific problems linked to particular research objectives, rather than by any geographical preference. Indeed, the European scope of a project seems prejudiced by the particular funding structure of the EU's FPs. Also, in new collaborations, considerations about the availability of financial resources sometimes outweigh preferences for particular potential collaborators (who, for geographical or other reasons are not eligible for inclusion in the grant). Furthermore, for the researchers, the particular mode of engaging into an EU funded network was presented as having serious drawbacks, such as having to spend a considerable amount of time on paperwork and administration. In other words, while it is true that the objective of the initiators had been the broadening of the pool of available samples for research on rare diseases, creating a Europe-wide biobank network was also seen as a 'necessary evil' to secure funding. The research objectives of the core group initiating the funding proposal partly compromised by the structures and tasks imposed on the researchers by the funding agency. On the other hand, funding agencies are capable of learning as well. As the ESFRI initiative shows, emphasis shifts from fostering short-term collaboration within Europe towards strengthening the international position of European institutions by enabling them to place themselves at crucial points in sustainable long-term research collaborations and infrastructures.

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Disclaimer

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Notes

1 The completion of the sequencing of the human genome is often seen as the end point of the Genomic Era and harnessed the beginning of the so-called 'Post-Genomic' one (focusing on other 'omics' such as proteomics, interactomics, etc). In this paper, we will not uphold this distinction but refer to the Genomic Era as the period starting with the Human Genome Project in the 1990s, including all its subsequent spin-offs.

2 Although the Nuffield Council on Bioethics is not an international organisation, its international reputation as well as the international attention attracted to its recommendations is considerable. The Nuffield Council was established by the Nuffield Foundation in 1991 as an independent advisory body funded by the Foundation, the Medical Research Council and the Wellcome Trust (see http://www.nuffieldbioethics.org/go/aboutus/page_2.html, accessed August 17, 2005).

3 Salter and Jones (2002, p.812) argue that the Convention echoes the Universal Declaration on the Human Genome and Human Rights and thereby provides bioethics with a formal legitimacy. In their paper they discuss the Convention in the broader setting of European governance. For a general critique on the Oviedo Convention see Mori and Neri (2001).

4 For further reading see Tallacchini (2006), van Veen (2006), March et al. (2001) and Austin et al. (2003).

5 The 'Subsidiarity Principle' means that what the smaller entity can do adequately should not be done by the larger entity unless the latter can do it better. It was first introduced in the Treaty of Maastricht (1992) as a general principle applicable to all areas of non-exclusive competence.

6 The EU does have, however, competence in the field of public health, based on Articles 129 and 152 of the 1993 Maastricht Treaty on the European Union, and the 1999 Treaty of Amsterdam. The EU institution primarily responsible for public health matters is the Health and Consumer Protection Directorate-General.

7 The mandate for this competence derives from Article 152 of the EC Treaty, and especially paragraph 4(a) referring to substances of human origin: "4. The Council, acting in accordance with the procedure referred to in Article 251 and after consulting the Economic and Social Committee and the Committee of the Regions, shall contribute to the achievement of the objectives referred to in this article through adopting: a) measures setting high standards of quality and safety of organs and substances of human origin, blood and blood derivatives; these measures shall not prevent any Member State from maintaining or introducing more stringent protective measures".

8 These (non-binding) opinions gain importance by being referenced in topically related directives.

9 We are grateful to Herbert Gottweis for making the transcription of this particular interview accessible to us.

10 Further information see http://cordis.europa.eu/esfri/home.html.

11 Further information see http://www.biobanks.eu/index.html.

12 In the context of this call, 'non-competitive' meant that only one application would be accepted. This was meant to encourage stakeholders to join forces and reach agreement on how to address prevailing issues of transnational significance (e.g., which best practice guidelines to follow) as early as during the process of proposal writing.

13 All interviews were conducted between 2005 and 2007. Protecting the privacy of our interviewees we indicate only their institutional affiliation and the year the interview was conducted (e.g. interview F, GenomEUtwin, 2006). All further details that could lead to the identification of the individual were omitted.

14 The methodological orientation is strongly guided by the interpretative approach towards the analysis of the interviewees' accounts and based on grounded theory (Clarke, 2005; Glaser and Strauss, 1967).

15 See http://www.eurobiobank.org (accessed December 20, 2005).

16 Deutsche Gesellschaft für Muskelkranke, see http://www.http://www.dgm.org/ (accessed May 25, 2007).

17 Association Française contre les Myopathies, see http://www.afm-france.org/ (accessed May 25, 2007).

18 See http://www.promocell.com/ (accessed May 25, 2007).

19 See http://www.genomeutwin.org (accessed August 2, 2005).

20 By April 2007, the Avon Longitudinal Study of Parents and Children (ALSPAC, UK), the Centre for Integrated Genomic Medical Research (CIGMR, UK), the Western Australian Genetic Health Project (WAGHP, Australia), the Danubian Biobank Foundation (involving six countries in Central Europe), the National Heart, Lung and Blood Institute (NHLBI, USA), the Cooperative Health Research in the Region of Augsburg bank (KORA-Gen, Germany), the Estonian Genome Project (Estonia), Generation Scotland (UK), the National Institute of Genomic Medicine (INMEGEN,Mexico), the National Institute for Health and Medical Research (Inserm, France), the LifeLines Cohort (the Netherlands), the Singapore Tissue Network (Singapore), the Taiwan Biobank Institute of Biomedical Sciences, Academia Sinica (Taiwan), and LifeGene (Sweden) had joined P3G as charter members.

21 See http://www.genomequebec.com/ (accessed May 25, 2007).

22 See http://www.genomecanada.ca/ (accessed May 25, 2007).

23 See http://www.eurobiobank.org/ (accessed December 20, 2005).

24 See http://www.genomeutwin.org/ (accessed August 2, 2005).

25 The online-catalogue is the manifestation of the 'critical mass', which included 140 cell collections, 534 DNA collections and 304 tissue collections by August 2005 (see http://www.eurobiobank.org, accessed December 20, 2005).

26 A 2003 special issue of *Twin Research* (Vol. 6, No. 5) was devoted to GenomEUtwin.

27 See http://www.p3gconsortium.org/ (accessed March 11, 2006).

28 Most of the actual work is done in the Core meetings, and later reported to the relevant International Working Group. The Cores are self-funded (which means that they do not rely on P3G funding), and are selected in an application procedure by the P3G Board. Each member of P3G can set up a Core.

29 Professor of Biomedical Computing Technology at the Karolinska Institute in Sweden and member of GenomEUtwin.