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Editorial

In these days all GeneBanc-collaborators and in particular those working at the Centre for Biomedical Ethics and Law (Leuven, Belgium) are intensively active in the preparations for the International Conference *New Challenges for Biobanks. Ethics, Law and Governance*, which will be held in Leuven (Belgium) on 18, 19 and 20 May.

During this conference experts will come together to discuss ethical, legal and governance issues related to biobanking. Among others the ethical and policy issues about the creation and organisation of the biobanks, the methods of obtaining and using samples and their related information, issues related to informed consent, privacy and confidentiality will be analysed.

More than 50 abstracts were submitted to the conference. The conference programme, which is now online on the website www.genebanc.eu, offers an alteration of plenary and parallel sessions, and brings together a large group of experts working in

the field. It is a meeting you should certainly attend. You can register for the conference on our website www.genebanc.eu

In this newsletter we offer three contributions. Jan Reinert Karlsen brings a contribution on aspects of ethical reflexivity in post genomic research biobanking. Darren Shickle and Marcus Griffin bring some conclusions on their work on ethics and governance of population and small scale biobanks. Petra Bárd reports about a recent judgment of the European Court of Human Rights. Two individuals complained for violation of their human rights, when the UK authorities continued to retain their fingerprints, DNA samples and profiles after criminal proceedings against them had ended with an acquittal or had been discontinued.

Looking forward to meet you at the conference,

Pascal.Borry@med.kuleuven.be

The Castle and the Desert: Aspects of ethical reflexivity in post genomic research biobanking

Can we be certain that we know what the ethical issues of research biobanking really are? The question itself is rarely, if ever asked by researchers and ethics experts probing the ethical, legal and societal issues (ELSI) of research biobanking. While this apparent lack of reflexivity seems to be a feature of the discourse itself, it was not in order to rectify the failures of others that made us ask this question in the first place.

Rather, it was our own failure to understand what the ethical issues of research biobanking in fact were that prompted the reflections documented in the research paper 'The ethical topography of research biobanking'. (Karlsen & Strand 2009)

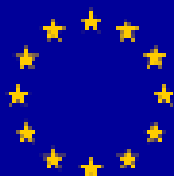
The present article is my attempt to recapitulate some of the questions and seminal ideas that provoked those reflections. In order to avoid that recapitulation turns into mere reiteration, however, my intention is to provide some reflections on why these questions were asked, why they seemed so important at the time, and more significantly, why I think they continue to be so important today.

Ethical land surveying

The reflections and ideas documented in the paper 'The ethical topography of research biobanking' actually commenced in the late fall of 2004, although a first draft was not produced before May 2005. At that time I had worked for a year as an ethical "land surveyor" in the research project *Mapping the language of research biobanks and health registries - From traditional biobanking to research biobanking*. (Solbakk et al. 2004) After four years of writing, three complete revisions of the draft, and one research project later, a draft was finally submitted and accepted for publication in the book series *Ethics, Law and Society*.

The reasons for the long and windy intellectual detours we undertook in order to complete a publishable draft are many, so many, that I am still not able to recount them all today. In lieu of the diversity of reasons, the difficult aspects of ethical reflexivity, however, stand out from the rest.

The allusion to Kafka's protagonist K. in *The Castle* (1926) is deliberate. K. is a land sur-





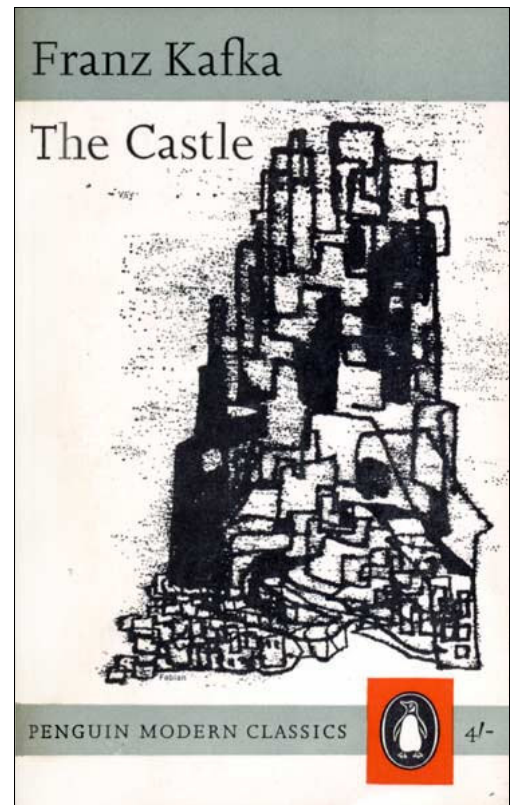
Jan Reinert Karlsen

veyor. He is summoned to conduct land surveying in a foreign land with alien customs that he neither understands nor is allowed to begin to understand. Upon arrival in a nameless village, K. finds out that his services are no longer required, indeed that they may never have been needed in the first place. In fact, throughout the novel it remains unclear whether K. has been summoned at all, let alone who is responsible for summoning him, or even why. The Castle looming over the village is, for reasons he does not fathom, inaccessible for him. Given that he may have been called upon, though not for the reason of conducting land surveying, K. embarks on a quest for the last scraps of meaning left of his assignment only to find out that the simplest of insights into its nature are countered with ever more convoluted bureaucratic gambits, leading to K.'s ultimate resignation. K. is never admitted access to the Castle.

At first sight it may seem surprising that the absurdity of K.'s situation should have anything to do with the situation of ELSI researchers: "By this allusion, do you suggest that ELSI researchers are called upon in order to conduct research on issues that have already been decided upon, and as such, not only are conducting a form of redundant research, but that it is the form of this redundancy that is one of the main reasons for being assigned to conduct it?" As surely as such a situation indeed would constitute an absurdity, the allusion may be interpreted in a number of ways.

It would hardly comprise a controversial statement to say that most ELSI researchers from time to time have fallen into doubt about their research assignments in particular and pondered over the question about the role played by ELSI research in general. While this doubt undoubtedly can take on as many forms as there are ELSI researchers, one possible articulation of this hesitation would be to ask whether one's assignment may not have been funded in order to facilitate emerging sciences and technologies (ESTs) rather than to foster critical perspectives, academic autonomy as well as critically assessed knowledge produced from those perspectives. In other words, it seems more important *that* the ELSI research is done, than *how* it is done, *why* it is done, or even *what* it criticises.

When working as an actual land surveyor, the topography, art, as well as possible assignments are givens. In ELSI research such 'givens' constitute an already established perspective – the official perspective, or map, if one wants. It would be surprising indeed, if ELSI research, in a similar manner to that of land surveying, was unable to define the ethical issues of post genomic research biobanking for itself; if the ethical topography already had been mapped by a given, official ethics; or if the only possible assignments were those in which the official map were tacitly taken for



granted. Would not ELSI research then stand at risk of being reduced to an unreflected form of sponsored research?

Ethical reflexivity in post genomic research biobanking

If the allusion to K. may serve as an access point to the nebulous roles that ELSI research may take upon in relation to ESTs, it is because the nebulous character of this role needs to be articulated as an aspect of the ELSI research itself: But, how does one incorporate this aspect into ELSI research practices? The genealogy of 'The ethical topography of research biobanking' began with this challenge of ethical reflexivity in order to ask for the ethical issues of post genomic research biobanking anew.

The carefully orchestrated publications of the human genome sequence variation (Sachidanandam et al. 2001; Venter et al. 2001) marked the first major success of industrial biology. A range of policies facilitating the construction of post genomic research biobanking was articulated to catch up with the rapid developments in order to exploit both actual and fictional possibilities arising from them. (E.g. Althingi 2000; Riksdagen 2002; Stortinget 2003) One might have suspected that the novelty of the situation would require new insights into the origins of the ethical issues surfacing from these newfound realities and possibilities. Instead, the ethical issues were determined as analogies of ethical issues arising in clinical research and transplantation medicine.

The epistemological problem of determining the ethical issues emerging with post genomic research biobanking in analogy with medical ethics are not trivial, but lead to a potential trivialisation of the ethical issues at stake. In 'The ethical topography of research biobanking' this problem was articulated as a problem of representation: "When represented as an issue of protecting the physical integrity of donors, it is surprising how research biobanking should inspire to ethical reflection at all. The miniscule intervention needed to collect a biological sample from which genetic information can be sequenced and digitally stored, hardly constitute a risk for anyone's "physical and mental integrity" (WMA 2000), perhaps except from severe cases of decidophobia, or depending on the method of harvesting, even aichmophobia (needle anxiety) and hematophobia. Hence, in the absence of the tangible physical and mental risks usually associated with human experimentation, a lot of the ethical babble on research biobanking has gravitated around issues on how much information should be given to donors, and how specific it needs to be for the consent to be ethically justified, or at least legally valid (see Hansson et al. 2006)." (Karlsen & Strand 2009)

While the mechanisms introduced by informed consent to some degree would protect the wellbeing of individuals against unauthorized breaches of their physical integrity, it seemed less likely that they would protect the interests of individuals, since these interests had been determined as *if* the context were medical.

One can only appreciate the differences of context, if one at the same time recognizes that the industrial revolution in biology had turned human biological material and its concomitant bioinformation into a natural re-

source, which now could be exploited for commercial ends by a nascent bioindustrial complex. Given this new outlook on the human body and its parts, and the unfathomable amount of person specific information biobanks now are able to digitalize, store and analyse, one can only begin to wonder what *the dignity of human beings* and *confidentiality* actually means in this context, not least the significance it may still be able to retain under such premises.

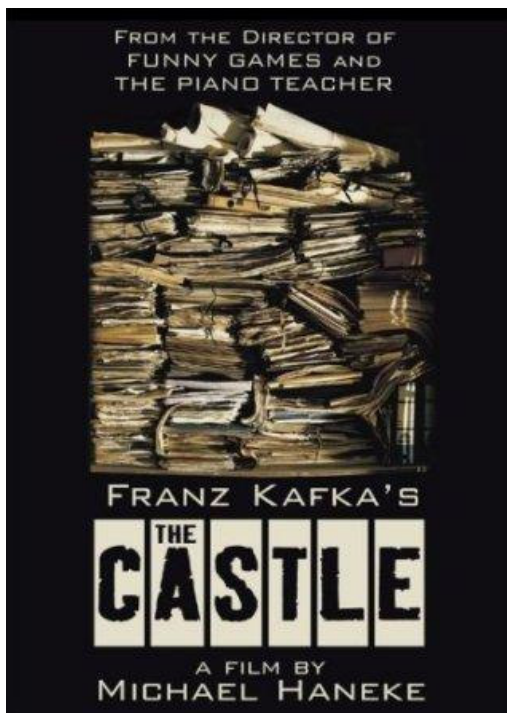
By employing the languages of medical ethics, policies have been articulated under the tacit assumption that similarity of words entails identity of concept, and that concepts are impervious to context when articulated as universal claims of ethics. The indeterminacy of these representations, however, enables them to take upon a range of unintended and morally dubious functions.

When writing 'The ethical topography of research biobanking' we began by mapping the indeterminacy of these socially constructed representations, focusing on their representationality and functionality:

'Biobanks' are represented as well defined, systematized and enclosed repositories, similar to the pathological collection at hospitals, while they are currently being hardwired into international research infrastructures (e.g. BBMRI; P3G; PHOEBE); 'donors' are represented as inherently altruistic persons who donate gifts, much in the same manner as blood and organ donation, while researchers are encouraged to become entrepreneurs on the 'donations'; informed consent is employed to protect the well being and interests of research participants while at the same time providing the mechanism for denying participants economic interests in their own tissue; the principle of 'non-commodification of the human body and its parts' is invoked to protect the dignity of human beings in a context where human biological material is represented as a natural resource for all but one of the stake holders (in combination with informed consent this principle provides industrial biology with 'ethical' access to gratis raw material); the obligation of 'confidentiality' is prescribed in analogy to the personal and sacred bond of the physician-patient relationship, although it is generally accepted that such obligations cannot be given since data security cannot be guaranteed.

An epilogue to a prologue

In lieu of what has already been said, an integral part of ELSI research is to add reflexivity to complex ethical, legal and societal issues emerging with scientific practice, knowledge and its applications. But how do we add it, and why is it so important? One needs to construct a critical perspective that allows one to determine the issues for oneself, while at the same



time allowing for a critical distance that is indispensable to it.

By establishing a critical distance to one's 'object' one is merely doing what all types of research strives to accomplish, including the biomedical research conducted on biobanks. Critical distance does not, however, provide any guarantees against misuse. Even the most critical of ELSI research can never attain imperiousness against being used for other ends than those intended: "This research has been subjected to the most thorough ethical criticism, and is therefore acceptable." It is neither the role of ELSI research to provide ethical labels to ESTs, nor to facilitate them.

On the positive side, reflexivity can provide some form of guaranty against tacitly accepting ethical issues as 'givens', as if the determination of these issues is value neutral, devoid of Real Political content and vested interests. By subjecting the official perspective, language, or map to destructive philosophical criticism, one is faced with an even greater commitment, i.e. that of providing critical perspectives, concepts and languages that enables us (as citizens, ELSI researchers and members of communities) to actually see beyond the scrapheap of progress-friendly ethical devices and consumer goods, and adopt a new form of gaze that is able to actually see the stakes of post genomic research biobanking in new light.

In the prologue to 'The ethical topography of research biobanking' we quoted Borges' aphorism "On Exactitude in Science" (1946) in order to characterise the relationship between representationality and functionality of maps. I will end these reflections with that quote, as it also marks the beginning of that research paper. "In that Empire, the Art of Cartography attained such Perfection that the map of a single Province occupied the entirety of a City, and the map of the Empire, the Entirety of a Province. In time, those Unconscionable Maps no longer satisfied, and the Cartographers

Guilds struck a Map of the Empire whose size was that of the Empire, and which coincided point for point with it. The following Generations, who were not so fond of the Study of Cartography as their Forbearers had been, saw that that vast Map was Useless, and not without some Pitilessness was it, that they delivered it up to the Inclemencies of Sun and Winters. In the Deserts of the West, still today, there are Tattered Ruins of that Map, inhabited by Animals and Beggars; in all the Land there is no Relic of the Disciplines of Geography." (Borges 1998, 325)

Perhaps the dilemma for the ELSI researcher must still remain, that in order to construct a critical perspective or tacitly adopting an existing one, he or she must either choose to live in the contourless shadows of a looming Castle, or among Animals and Beggars under the scorching sun of the Deserts of the West.

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The **Center for Ethics and Law in Biomedicine** at the **Central European University, Budapest** will host the Second International Workshop between **6 - 8 April 2009** on the 'Anonymisation and Pseudonymisation as a Means of Privacy Protection' organized in the framework of the European Commission funded tiss.EU project. The workshop will focus on five jurisdictions: Bulgaria, the Czech Republic, Hungary, Slovakia and Romania.

For detailed information please visit the project website <http://www.tisseu.uni-hannover.de/index.php>."

Ethics and governance of population and small scale biobanks. Initial conclusions of GeneBanC Workpackage 2

The research conducted as part of Workpackage 2 has revealed a wide variety of biobanks and highlighted the difficulty in classifying them. While there is some merit in thinking about biobanks in terms of whether they are small versus large, prospective versus retrospective or single disease versus multi-disease, early on it became clear that the ethics and governance issues should not be restricted to such a classification system.

Retrospective case-control tissue collections

The term biobank is relatively new. Historically most genetic research utilised retrospective case control methodologies. They were usually just described as tissue collections developed by a single or a few interested clinician(s). Typically clinicians would collect samples from patients with a specific disease and from a matched control group, and looked for differences in gene frequency between the two groups in order to identify potential genes in the causation pathway for that disease. They tended to be small in size and used to conduct linkage studies to identify genes (usually with high penetrance) for rare disorders. For very rare diseases, it may not have been possible for a single research group to collect a large enough number of samples, and so it was necessary to seek out research teams elsewhere with similar collections that they were willing to share.

Prospective cohort studies

Case control studies are relatively cheap and quick to do, and are also well suited for rare diseases, but are not so effective when examining rare (genetic) exposures, for exploring gene-environment interactions when exposure data may be subject to recall bias. There has therefore been a shift to establishing prospective cohort studies. Even for common diseases, cohort studies need to be large in order to have enough end-points (i.e. people who develop the disease) to study. The ethics and governance issues associated with a case-control study are in principle straightforward. As part of the informed consent process, it is possible to explain to participants what is expected of them, how data and samples will be used, by whom, and what are the likely benefits. For many longitudinal studies, this is also relatively uncomplicated, albeit the timescales are much more elongated. However, for many prospective genetic cohorts, many of these information elements are less clear or completely unknown. There has been much debate in the literature about the ethics of blanket consent or consent waivers, whereby individuals are asked to donate to a biobank for research purposes and researchers which can only be specified in general terms.

Networks

There have been moves on national and international levels to network smaller biobanks in order to increase the size, improve quality and reduce cost of their research platforms. This presents many challenges in terms of governance and ethics and led to an increasing drive for harmonisation. The networking phenomenon is at the heart of modern biobanking. Networking is almost an absolute for biobanks to flourish in the new Century. As experience and understanding has grown, it has become clear that many biobanking initiatives have failed to deliver on the high expectations and claims made for them. Networks seek to address the inadequacies of biobanks. The main areas of difficulty addressed by networking are: size, quality, cost, ethics and governance. Within Workpackage 2 we have observed different forms of networks that we have categorised as follows: 'Storage' networks, 'Power' networks, 'Library' network, 'Recruiting' networks, 'Expertise' networks, 'Harmonisation' networks, and 'Networks of networks'.

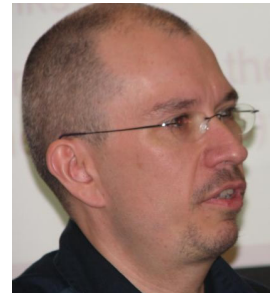
'Storage' networks

Some networks have developed mainly as a storage solution. The cost and speed of genetic procedures have improved significantly over the last decade, evidenced by the Human Genome Project coming in ahead of schedule and below budget. Nevertheless, the costs associated with establishing and maintaining a biobank are significant. Storing samples in a freezer in a corner of a laboratory is no longer sufficient. Thus, smaller collections are working together for economies of scale to utilise cutting edge technology for the processing, storage and retrieval of samples. Any other connections between them in terms of research may be limited or non-existent. These *storage networks* are mainly collaborations to have a shared facility to reduce cost and raise quality. Typically they may have a focus in a relatively small geographical area, bringing together tissue collections of different sorts in an institution or within a region. As a requirement to use the storage facility, some *storage networks* require a minimum standard of informed consent, and so there may be some convergence in ethics procedures and legal requirements.

'Power' and 'library' networks

Other networks bring together biobanks researching similar diseases, in order to increase statistical power to research rare diseases or exposures. These *power networks*, may share samples or effort in recruitment.

Many *power networks* maintain their samples within their own biobank, but publicise what is contained within them, so that other research



Darren Shickle



Marcus Griffin

teams who subscribe to the network can request access to material for their research. This similar to how a library can request books via inter library loans. They are typically international collaborations, where it would not be efficient or appropriate to send samples longer distances to a single storage facility. These *library networks* are only as effective as the effort invested in uploading and maintaining information about the content of collections. *Library networks* also have to cope with problems with transferring samples between countries which can have incompatible rules around ethics and legislative requirements. Thus, these issues typically consume a lot of attention when the network is established.

'Recruiting' networks

Recruiting networks attempt to share costs and effort in recruitment. Typically all the material and data are stored in a single location, but sometimes there can be multiple storage sites. But there is always a central coordinating hub for network administration. Externally, it may appear to be a single biobank, but often they are national initiatives to encourage clinicians and researchers to collect samples within a network rather than set up their own smaller collections with all of their problems of scale and limited expertise.

'Expertise' networks

Expertise networks allow networks to share experience and good practice. They may be *bottom-up* with biobanks spontaneously coming together to share experience between each other and with new biobanks being established. Alternatively they can be more *top-down* with funding provided by a national or international body to facilitate the joint working. *Expertise networks* can share expertise on the processing and storage of data and samples, training of junior researchers etc.

'Harmonisation' networks

Many are *harmonisation networks*, by publicising procedures that existing biobanks are using, as well as saving newer biobanks having to reinvent-the-wheel, it means that sharing data and tissue will be easier at a later date as there will be more alignment in protocols.

However, many *expertise networks* have a significant function around ethics and governance. Harmonisation of ethics procedures such as informed consent will help sharing of samples between countries with different legislative and governance frameworks, but also allowing the pooling of expertise on ethics and governance issues for biobanks which may not have the time or expertise to develop high quality effective ethics and governance procedures.

'Networks of Networks'

Many networks have a combination of these various characteristics. Indeed, the drivers of size, quality, cost and ethics and governance are increasingly leading to *networks of networks*.

Biobanks: a new ethics and governance paradigm for researchers

The problem has been that many genetic researchers, have had limited training in ethics and have struggled to adapt to the new ethical challenges of biobanks. Instead many have attempted to adapt ethics procedures from the old paradigm. In order to establish a case control study, a small group of researchers would typically submit an application to a funding body via a standard call for proposals. Large biobanks are expensive, and therefore funding arrangements also tend to be different. Given the size of the budget more than one funder may need to sponsor the project. With such a large financial commitment, extra scrutiny is required at all stages of planning, establishing and maintaining the biobank to assure the investment.

Often governments are involved to provide funding or because legislation is required. Political scrutiny can further complicate the governance arrangements. Although in some countries, government backing for a biobank has been driven by national jingoism to give impetus to a country's research and biotech industry, rather than being based on a sound business case with adequate infrastructure to deliver its scientific aims.

Given the stakes involved for genetic research if adverse media publicity about a biobank leads to public mistrust and hence low response rates, the governance arrangements tend to be particularly tight. Biobanks typically involve many more academic organisations, each of which may have different ethics procedure and governance arrangements. Robust governance arrangements are sensible, and are in contrast to genetic research conducted under the traditional approach in which researchers had limited scrutiny for an ethics committee once the initial protocol was approved and virtually no monitoring from the host organisation and funders as long as the project stayed within budget and produced its deliverables and final report. However for some biobanks ethics and governance arrangements have become overly restrictive and could actually be a threat to the viability of the biobank and producing benefits for the public interest.

It is increasingly recognised that many biobanks are not big enough or will be inadequate to use for research on anything but the most common diseases. Therefore increasingly networks are forming to increase sample size and number of endpoints. However, each biobank would have used a slightly, or sometimes very

different consent procedure and potentially if part of an international biobank, will have worked within a different ethics and legal framework.

Thus there is a danger that the ethical imperative to respect the donor of tissue and data as an autonomous agent by seeking informed consent to use their involvement to conduct defined research for defined purposes has been lost in a scramble to be seen to be at the forefront of genetic research with a large biobank and then to seek mergers into networks in order to sustain viability.

Biobanks and the ethics crunch

Prior to de-regulation of the financial sector in the 1980s, most banks were small having an intimate knowledge of their client's histories and aspirations. Deregulation led to demutualisation of building societies and credit unions. Mergers led to increasingly bigger banks, dependent on the international money market rather than on the small but regular and dependable saver. Securitisation was the process by which assets of varying value were bundled together and sold on, without sufficient scrutiny as to whether the debts could be repaid. The credit crunch that followed the realisation that the bank's business model was unsustainable is well documented. Hopefully biobanks will not suffer a similar fate and that biobank networks are not a way of 'securitising' tissue samples of uncertain scientific value and will deliver a return on research funding investment. The financial regulatory structure was insufficient to address to rapid change and growth in the banking industry. It is important that the ethics and governance regulatory framework is not found similarly wanting for genetic biobanks.

Initial Workpackage conclusions

Initial conclusions for Workpackage 2 are as follows:

- There is an increasing demand for rigorous ethics and governance in every country visited.
- In some instances the desire for ethical rigour has created an unduly bureaucratic environment that has caused biobanks to struggle to function properly.
- The ethics and governance arrangements for a biobank depend on the legislative environment and the history surrounding the development of policy and legislation.
- Ethics and governance arrangements are also influenced by the interaction between the public, state, and the scientific community. In particular, the degree to which people trust the scientists and institutions of their country and the extent to which they see the potential for public goods. However we have also observed complicity between government and scientists, with both having a vested interest in easy access to personal information from the public.
- Attitudes towards confidentiality, data protection and consent vary between countries.
- The ethos of the scientific community and the way they regulate themselves, both formally and informally via peer pressure varies between countries and according to the characteristics of the biobank.
- Attitudes to Europe and European legislation can also influence governance of a biobank.
- Even in countries where there is little legislation or commitment to bioethical considerations, there is financial pressure to take considerations around ethics and governance seriously. Both framework 6 and even more so framework 7 have strict stipulations around how ethics and governance should be carried out. Thus, researchers wishing to participate in projects with European funding must address such issues.
- The influence of 'famous' biobanks, in particular UK Biobank (although the Icelandic biobank seems to have had less impact). Many smaller biobanks are very aware of the time and money that has been spent establishing ethics and governance arrangements for UK Biobank and hence have tended to use these as a benchmark of quality and have copied these procedures where practicable, resources etc allowing.
- Efforts towards networks and harmonisation. This is partly in order to share the workload of developing ethics and governance, which scientists find complicated and time consuming, and also bears risks if they get it wrong. Harmonisation has also been driven by a need to develop common systems (technical, procedural and ethical) to allow them to share data and material. Scientists are realising that biobanks will need to be larger than power calculations may have initially suggested.
- Newer biobanks are paying considerably more attention to ethics and governance issues, reflecting a change in political and regulatory environment, media scrutiny and public attitudes.
- Scientists seem to behave differently according to the funding of the biobank. Funding by government or a national charity is more likely to lead to scientists talking about the biobank in terms of a 'public resource' rather than a research project belonging to a group of scientists/a university in which they run the management committee and control access to samples. This influences whether the academics feel a direct obligation to the public or whether the biobank is a resource for their own personal research, and hence has only indirect benefits for the public. Researchers invest more of their time on media publicity and supporting education initiatives within national biobank initiatives. This difference in attitude towards public participation was observed for researchers who were involved in both sorts of biobank funding.

On **18 and 19 May 2009** the GeneBanC-project is organizing an **international conference** with the aim to discuss some of the complex and challenging issues that are linked to the ethical, legal and social issues related to biobanking. On **20 May 2009** the GeneBanC-project is organizing an interactive meeting in which various stakeholders related to biobanks will be invited. Both meetings will take place in Leuven, Belgium.

Registration for the conference can be done through the website www.genebanc.eu

International Conference. New Challenges for Biobanks. Ethics, Law and Governance

Leuven, Belgium, May 18-20, 2009

Plenary Sessions 18 and 19 May 2009

Welcome: Kris Dierickx (K.U.Leuven)

PLENARY SESSION 1: Biobanking and governance

Chair: Herbert Gottweis (University of Vienna, Austria)

- Kurt Zatloukal (University of Graz, Austria)

PLENARY SESSION 2: Biobanking and confidentiality

Chair: Jan Helge Solbakk (University of Oslo, Norway)

- Lori Andrews (Chicago-Kent College of Law, Chicago, USA)
'Biobanks: New Challenges for Human Research Policies'
- Paula Lobato de Faria (New University of Lisbon, Portugal)
'Confidentiality in Biobanks – Origins, present and future of a legal myth'

PLENARY SESSION 3:

Harmonisation of the regulatory framework of biobanks and privacy protection. Chair: Herman Nys (K.U.Leuven, Belgium)

- Elisabeth Rynning (Faculty of Law, Uppsala University, Sweden)
- Judit Sandor (Center for Ethics and Law in Biomedicine, Central European University, Hungary)
From Private to Public? Legal Concepts of the Right to Privacy and Ownership in the Legal Regulation of Biobanks

PLENARY SESSION 4: Regulatory framework

Chair: Darren Shickle (Leeds University, UK)

- Laurie Graemie (School of Law, University of Edinburgh, UK)
- Bartha Maria Knoppers (University of Montréal, Canada)
Access to Population Biobanks

PLENARY SESSION 5: Forensic DNA

Chair: Kris Dierickx (K.U.Leuven, Belgium)

- Jean-Jacques Cassiman (K.U.Leuven, Belgium)
- Robin Williams (School of Applied Social Sciences, Durham University, UK)

Parallel Sessions 18 and 19 May 2009

More than 40 presentations in PARALLEL SESSIONS ON:

- Governance
 - Country reports on Biobanks
- Forensic DNA Analysis and Biobanking
- Informed consent for biobanking research
 - Commercialization
- Philosophical perspectives on biobanks
- Privacy and access to genetic research data

Stakeholder meeting 20 May 2009

Welcome: Pascal Borry (K.U.Leuven)

Moderator: Marc Leys

MORNING SESSIONS: Privacy and transnational practices

Short statements: Herbert Gottweis, Judit Sandor, Jan Helge Solbakk

Discussion in small groups and panel discussion

AFTERNOON SESSIONS: Biobanking and harmonization

Short statements: Herman Nys, Darren Shickle, Kris Dierickx

Discussion in small groups and panel discussion

Venue

The conference and the interactive stakeholder meeting will take place in the Faculty Club (www.facultyclub.be) in Leuven (Belgium). The conference hotel is the Begijnhofcongreshotel (www.bchotel.be). Reservations should occur directly with the hotel. On the website www.genebanc.eu you can find a registration form. You will be able to register for the conference at the conference rate: 155 euro per night for one person room (instead of 230) or 180 euro for a two persons room (instead of 255 euro). For other hotels in Leuven, please consult the website www.leuven.be

Registration

Participation in the conference costs 130 euro if you register before April 1, 2009. After April 1 participation in the conference will cost 180 euro. This includes the coffee breaks, a dinner on Monday evening 18 May, the lunch on Tuesday 19 May and the lunch on Wednesday 20 May. It also includes a conference book, which will be sent to all participants a few months after the conference. This low conference fee is possible thanks to the support of the European Commission. All questions with regard to the registration of the conference should be directed to Annemie.Patyn@med.kuleuven.be



Petra Bárd

Case of S. and Marper v. The United Kingdom

On 4 December 2008 a Grand Chamber of the European Court of Human Rights (ECtHR) delivered its judgment in the case of *S. and Marper v. the United Kingdom*. (4 December 2008, Application numbers 30562/04 and 30566/04.) After having deliberated in private twice during the year, the Court held in a unanimous decision that the United Kingdom was in violation of Article 8 of the European Convention on Human Rights (ECHR).

Both applicants complained under Articles 8 and 14 ECHR violation of their human rights, when the UK authorities continued to retain their fingerprints, DNA samples and profiles after criminal proceedings against them had ended with an acquittal or had been discontinued.

The legal basis of sample taking and storage is originally laid down in Section 64 of the Police and Criminal Evidence Act of 1984 (PACE). According to the first version of the provision it was unlawful for the police to retain samples of individuals acquitted or if the charges discontinued, however the date by which samples were to be destroyed was rather unclear: they had to be deleted “as soon as practicable after the conclusion of the proceedings.” Section 82 of the Criminal Justice and Police Act of 2001 then modified Section 64 PACE and dramatically changed the rules, which in their current form expressly allow for the retention of fingerprints and samples even after they fulfill their original purposes. The retained samples may be used in the future for crime prevention, detection, investigation and prosecution purposes. Both applicants fell under the scope of this provision.

S. was charged with attempted robbery in January 2001, at the age of eleven. His fingerprints and DNA samples were taken. S. was acquitted in June 2001. The other applicant, Mr Michael Marper, was around forty years of age when arrested in 2001 and charged with harassment of his partner. His fingerprints and DNA samples were taken. The case has been discontinued, since before a pre-trial review he and his partner got reconciled, and the charge was not pressed.

Both applicants asked for their fingerprints and DNA samples to be destroyed, but in both cases the police refused. The applicants applied for judicial review of the police decisions. Both applications as to the destruction of fingerprints and DNA samples had been refused at each appeal level, until the House of Lords’ decision became final and binding.

The House of Lords as the final national instance gave examples of cases where the re-

tention of samples had been useful. In 1999, in the case of “I” for example the DNA information from a perpetrator matched with that of “I” in the DNA database. The sample of “I” should have been destroyed, but had wrongly been kept. “I” then pleaded guilty to rape and was sentenced. Statistics show that almost 6,000 DNA profiles had been linked with profiles derived from crime-scene samples that would have been destroyed according to former provisions. The offences include among others 53 murders, 33 attempted murders, 94 rapes, 38 sexual offences, 63 aggravated burglaries and 56 cases drug cases.

Disagreement

Baroness Hale of Richmond disagreed with some aspects of the majority opinion written by Lord Steyn. In her view the retention of fingerprints and DNA amounted to an interference by the State with a person’s right to respect for his or her private life and therefore required justification under the ECHR. She considered DNA and fingerprints as parts of informational privacy and stated that it was difficult to imagine anything more private than the knowledge of someone’s genetic make-up. Baroness Hale of Richmond in her concurring opinion also suggested a distinction between fingerprints and DNA when it came to the justification of state interference. The European Court of Human Rights accepted the majority of her arguments.

After having given an overview of the facts and procedural history, the ECtHR summarized the relevant laws starting with the above mentioned PACE. Other relevant domestic laws include the Data Protection Act of 16 July 1998 that gives effect to the European data protection Directive 95/46/EC. The institution of the Information Commissioner has been created according to the Data Protection Act. The Commissioner is entitled to promote good practices and to make so-called enforcement notices with this regard. It is a criminal offence not to comply with such orders. Relevant domestic instruments also include the Retention Guidelines for Nominal Records on the Police National Computer of 2006 designed by the Association of Chief Police Officers in England and Wales. These Guidelines do not talk about destruction, but mainly deal with access to data. The Guidelines set different degrees of access to information contained in the Police National Computer system. Data on persons not convicted, and information on convicts after a certain period of time which varies between 5 and 35 years, are automatically “stepped down,” which means that this information is accessible only by the police. Information on convicts who had committed the most serious crimes are never “stepped down.”

The Court also enumerated the laws in the Council of Europe member states the majority of which allows compulsory taking of fingerprints and DNA samples in the forensic context. From among these countries most attach the permissibility of DNA and fingerprint taking to the suspicion of serious crimes. The requirement is usually that the crime by which the person is suspected shall be punishable by imprisonment in order for the police to be allowed to take the sample or the fingerprint. As to the destruction of samples, most states having forensic biobanks require information to be destroyed automatically upon acquittal or after discontinuance of the criminal proceedings. Exceptions from these rules are very limited. The storage of DNA profiles of convicts is allowed for shorter or longer, but in all cases for definite periods of time after the conviction or after the convict's death. There are complaint system mechanisms established in these countries for the destruction of samples or the deletion of profiles. The United Kingdom is the only member state which allows for the systematic and indefinite retention of profiles, samples of suspects and convicts, and where there is no challenge mechanism built into the system.

Convention of 1981

Beside the European Convention on Human Rights, Council of Europe member states are also bound by the Convention of 1981 for the protection of individuals with regard to automatic processing of personal data, which entered into force for the United Kingdom in 1987. It defines "personal data" in Article 2 quite generously, as "any information relating to an identified or identifiable individual ('data subject')." Article 5 lays down the quality of data requirements to meet, like the requirement that automatically processed personal data shall be stored and used only for specified and legitimate purposes, and that these data shall be "adequate, relevant and not excessive in relation to the purposes for which they are stored". Importantly, this provision also states that personal data are to be preserved in a form that ensures that the identification of data subjects is not possible for longer periods than required for the original purpose of information storage.

Still in the framework of the Council of Europe Recommendation No. R(87)15 regulating the use of personal data in the police sector is even more specific when it comes to the forensic use of data. Principle 2 lays down the purposes for which data may be gathered: permissible forensic purposes are the prevention of a danger, which must be real, or the suppression of a specific criminal offence. The Recommendation allows for exceptions if provided for by national law. The length of storage according to Principle 7 should be linked to necessity, i.e.

data should be deleted if they are no longer necessary for the original purposes for which they were acquired and stored. In this regard special attention is to be given to the following: "the need to retain data in the light of the conclusion of an inquiry into a particular case; a final judicial decision, in particular an acquittal; rehabilitation; spent convictions; amnesties; the age of the data subject, particular categories of data."

Recommendation No. R(92)1 is dealing specifically with the use of analysis of deoxyribonucleic acid (DNA) within the framework of the criminal justice system. Point 3 states that samples and profiles may only be used for the purpose of the investigation and prosecution of criminal offences. Any contrary or additional use would be in violation of the law, except if samples or profiles are needed for research and statistical purposes, and if it is made sure that the identity of the individual cannot be ascertained, i.e. if names or other identifying references are removed prior to the data's use in the extra-forensic context. Point 4 stresses the rule already existing under the Convention that the circumstances of sample taking and analysis are to be laid down in domestic law, in some cases specific authorisation from a judicial authority being needed. Point 8 limits the storage of samples and data: according to the provision they shall not be kept after a final decision is rendered, except if necessary for purposes which are directly linked to the original purposes for which they were collected. A mechanism shall be set up to ensure that samples and profiles are deleted when no longer necessary. A general exception from this rule is where the individual has been convicted of serious offences against the life, integrity or security of persons, in which cases strict storage periods have to be determined by domestic law. Samples and profiles may only be stored for longer periods either if the individual concerned so requests, or if the sample cannot be attributed to an individual (typically crime scene samples). Another general exception is when samples are gathered for state security purposes: in this case samples and derived information may be stored even if the person concerned has not been charged or convicted of an offence. Even in such cases strict storage periods have to be defined by domestic law.

In the European context the Court reiterated the Prüm Treaty on the stepping up of cross-border cooperation, particularly in combating terrorism, cross-border crime and illegal migration signed by seven European Union Member States on 27 May 2005 dealing among others with the exchange of DNA information and fingerprints. (Interestingly the Court did not mention the two instruments which transferred the Prüm Treaty into European Union Law: Decision 2008/615/JHA of 23 June 2008 on the stepping up of cross-border cooperation, par-

ticularly in combating terrorism and cross-border crime and Council Decision 2008/616/JHA of 23 June 2008 on the implementation of Decision 2008/615/JHA on the stepping up of cross-border cooperation, particularly in combating terrorism and cross-border crime.)

In the framework of the European Union, Directive 95/46/EC of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data is relevant. The Directive reiterates Article 8 ECHR, the Data Protection Convention and remembers that data protection is also among the general principles of Community law. The Court reminded of Article 13 of the Directive which allows Member States to adopt laws to restrict the scope of certain rights laid down in the Directive when such a restriction is necessary for the prevention, investigation, detection and prosecution of crimes.

The Court also referred to a Council framework decision 2008/977/JHA of 27 November 2008 on the protection of personal data processed in the framework of police and judicial cooperation in criminal matters which obliges Member States to establish appropriate time limits for the erasure of personal data or for a periodic review of the need for the storage of the data.

The Court considered it to be useful to look into non-European jurisdictions. Most notably, in the case of *R v. RC* (*R v. RC* [2005] 3 S.C.R. 99, 2005 SCC 61) the Supreme Court of Canada held that in the light of the principles and objects of youth criminal justice legislation the retaining a juvenile first-time offender's DNA sample on the forensic biobank was grossly disproportionate. The Court then analyzed the case under Article 8 ECHR.

The ECtHR adhered to its own case-law when underlining that the concept of "private life" is a broad term which cannot be defined precisely. It covers both the physical and psychological integrity of an individual. Even the mere storing of data relating to one's private life amounts to an interference within the meaning of Article 8, irrespectively of the further use of the stored data (*Leander v. Sweden* of 26 March 1987, Application number 9248/81, *Amman v. Switzerland* of 16 February 2000, Application number 27798/95). According to the ECtHR in the present case all types of stored information, i.e. fingerprints, DNA profiles and cellular samples, constituted personal data within the meaning of the Data Protection Convention. There are however considerable differences among those data: the ECtHR made a distinction between fingerprints and DNA already in its earlier case-law, because of the stronger potential for future use of the latter. (*Van der Velden v. the Netherlands*,

admissibility decision of 7 December 2006, Application number 29514/05) As to genetic data, the Court underlined that they may be used for other purposes than mere identification, that it contains highly sensitive information concerning one's health status, that it may identify possible genetic links between individuals, and may adversely affect relative's data protection. Therefore the retention of genetic data *per se* may give rise to justified individual concerns. This is not eased by the fact that at the current state of knowledge a fairly complicated technology is needed to "read" such information or by the fact that pieces of information are coded.

In relation to fingerprints, the Court found it necessary to review its earlier case-law. In *Kinnunen* (*Kinnunen v. Finland* of 15 May 1996, Application number 24950/94) the Commission decided that the storage of fingerprints and photographs did not constitute an interference with private life. This finding has been overruled in relation to photographs in *P.G. and J.H. v. the United Kingdom* (*P.G. and J.H. v. the United Kingdom* of 25 September 2001, Application number 44787/98). Now the Court overruled *Kinnunen* in relation to fingerprints as well, and held that the storage of fingerprints, just like the retention of photographs and DNA, also constitutes an interference with private life. This is not changed by the fact that the identity of a person whose fingerprints are retained is not directly obvious to the untutored eye and without a comparator fingerprint. In sum, the Court acknowledged the difference between the ways DNA and fingerprint storage may interfere with an individual's privacy due to the fact that sensitive information, such as one's ethnic origin, health status may be derived from genetic data. This difference however did not prevent the ECtHR from concluding that all types of data in the given case did constitute an interference with private life. The next issue to be determined was whether such an interference was justified, i.e. whether it was in accordance with the law, whether it pursued a legitimate aim, and was necessary in a democratic society.

According to the Court's case-law, in order for a rights limitation to be in accordance with the law, the law authorizing the rights restriction has to have a basis in domestic law, must be in line with the rule of law, and it must be adequately accessible and foreseeable, so that the individual may regulate his conduct accordingly without the need for any further advice. In order to meet these requirements, national law has to afford safeguards against arbitrariness indicating with sufficient clarity the powers, i.e. the scope of discretion conferred on the competent authorities, and the manner and conditions for the exercise of powers. In the Court's view Section 64 PACE can be seen as a clear legal basis for the

interference, however the conditions under which storage and use are permitted, are less clear. The purposes for which DNA samples and fingerprints may be used, like the investigation of an offence or the conduct of a prosecution, and especially the purpose of crime prevention and detection are too vague, and therefore may give rise to an extensive interpretation. The Court compared the storage of DNA and fingerprints to telephone tapping, secret surveillance and covert intelligence-gathering, and underlined in this context that it was crucial to lay down clear, detailed rules, and minimum safeguards among others on the duration, storage, use, destruction of information, access of third parties, procedures for preserving integrity and confidentiality of information, and on the guarantees against abuse and arbitrariness. The Court however did not stop the examination at this point, but noted that all these issues concerning the “prescribed by law” requirement of the interference are closely linked to the question whether the interference in question was necessary in a democratic society.

The Court excepted the arguments of the Government concerning the second prong of the justification of interference test: the Court agreed that the limitation of private life, i.e. the retention of fingerprints and DNA pursued the legitimate purposes of crime detection, identification of future offenders, and as a result crime prevention.

The case failed at the last prong of the test: the limitation was not considered to be necessary in a democratic society. The Court reiterated its case law on this test: for an interference to be necessary in a democratic society for a legitimate aim, it must answer a pressing social need, must be proportionate in relation to the aim to be pursued, and the reasons for the limitation must be relevant and sufficient. A certain margin of appreciation is left to the Member States, the width of which depends on the nature of the Convention right at issue, and that of the interference, the right’s importance for the individual, and the aim to be achieved. The margin is narrower in cases where the right in question is important for the exercise of one’s intimate or key rights, and also where an important aspect of an individual’s existence or identity is at stake. The margin is wider, whenever there is a lack of consensus as to the breadth of the right in the Council of Europe member states.

The protection of personal data is a crucial aspect of the right to respect. Safeguards must be even stronger against excessive use of data and have to ensure that they are used for a well defined purpose, when data are processed automatically, and if information is used for police purposes. Even more protection is needed for certain categories of data, sensitive data, like genetic information. National law

also has to guarantee safeguards against misuse and abuse.

The interests of the data subjects may nevertheless be outweighed by a legitimate interest, and the fight against crime and terrorism is certainly such. The issue for the Court is whether the retention of fingerprints and DNA of persons suspected, but not convicted of certain criminal offences was justified or not under the limitation clause of Article 8, paragraph 2 ECHR.

The Court recalled that England, Wales and Northern Ireland are the only jurisdictions within the Council of Europe, which allow the storage of fingerprints and DNA of any person who is charged with any offence, for indefinite periods of time, without judicial review. The Court also mentioned the regulation of Scotland as a positive example. The Scottish Parliament adopted a law which allows the retention of the DNA of unconvicted persons only for maximum three years, with the possibility of extension for another two years, if the convicts are adults and had been charged with violent or sexual offences.

The UK Government explained its unique position in Europe with the fact that they are pioneers in the forensic use of genetic information and other states have not yet established similarly efficient biobanks for crime prevention purposes. The Court however saw the UK’s pioneering role differently. It held that the alone standing position of the UK much rather meant on the one hand that there was a strong consensus among the Council of Europe member states to guarantee important safeguards against the use of bioinformation, and therefore there was little margin of appreciation left to the state. On the other hand the ECtHR warned that any state claiming a pioneering role in such a delicate matter has heightened responsibility to draw a balance between the competing interests.

Then the Court looked into the statistics by which the Government argued for the necessity of the rights restriction. The ECtHR accepted the argument that the 2001 extension of the database under the new rules contributed to crime detection and prevention, however it did not find the statistics convincing. Along the lines of the argumentation of the Nuffield Report, the Court stated that there is no sufficient link between crime scene sample matches and the retention of samples of unconvicted persons.

The Court thus found the lack of an independent review mechanism for the justification of retention, and the “blanket and indiscriminate nature of the power of retention”, which is irrespective of the nature and gravity of the offence, unacceptable.

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The last few years have witnessed an important expansion of collection and processing of human biological samples and of the related information data. Biobanks are huge repositories of human biological specimens and have a strategic importance for genetic research, clinical care and future treatments. Genebanc is a Specific Targeted Research Project (STREP) funded by the European Commission in the Sixth Framework Programme. This research project aims to investigate the ethical, legal and social issues of three types of biobanks: classical banking, population banking and forensic DNA databases.

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The ECtHR mentioned the likelihood of stigmatization due to the perception that those whose samples are on the database are not seen as innocent. This assumption is reinforced by the fact that their data are kept indefinitely, just like the information on convicted persons. The Court rejected the argument that the retention does not depend on guilt, especially since volunteers – who are not guilty, just like those whose cases have been discontinued, or who have been declared innocent by the judiciary – may ask their samples and fingerprints to be destroyed, whereas previous suspects may not.

The Court also remembered Article 40 Section (1) (viii) of the UN Convention on the Rights of the Child of 1989 on the heightened need of privacy protection in the criminal-justice sphere, and held that the retention of unconvicted persons' data may be especially harmful if the then suspect is a minor, like S. in the present case. When entering into the special dangers of applying the challenged rules to children, the Court also underlined a finding of the Nuffield Council, which proved the overrepresentation of young persons and ethnic minorities in the biobank.

On the basis of the above the Court concluded that the UK overstepped its margin of appreciation, and that the blanket and

indiscriminate nature of retention of the fingerprints, DNA samples and profiles of persons suspected but not convicted, as applied in the case of S. and Mr. Marper failed to strike a balance between the competing public and private interests, it constituted a disproportionate interference with the applicants' right to respect for private life and could not be regarded as necessary in a democratic society. The ECtHR concluded that the state's broad access to the sensitive personal data at issue and the insufficient protection against the misuse or abuse of such data constituted a violation of Article 8 ECHR.

Applicants argued that there was a violation of Article 14 ECHR in conjunction with Article 8 of the Convention, since there was a prejudicial and improper distinction made between the samples of persons who were supposed to be presumed as innocent. The Government argued that all those in analogous situation were treated the same. The Court held that since it found the state to be in violation of Article 8 it was not necessary to examine the application under Article 14.

The request on non-pecuniary damages because of the emotional harm suffered was rejected by the Court, which found that the ruling on the violation of the Convention was in itself sufficient just compensation.