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Petra Bárd*

The Force of Law: Genetic Data Protection in Central and Eastern Europe

ABSTRACT

During the past decade the collection and processing of human biological samples and that of related data gained an increasingly important role in both medical research and the forensic field. The European Union legislator tried to keep up with this phenomenon, and attempted to reconcile freedom of research in the classical biobank context and the principle of availability in the criminal context with European Union-wide data protection safeguards. In the lack of a sufficiently homogeneous legal framework European jurisdictions greatly differ in regulating the protection of genetic data. Two main country groups can be identified: Member States can be grouped along the question whether they have or do not have specific biobank laws. In countries that do have such laws, comparison is easier, and they are following international standards. Whenever such specific laws are lacking, not only the identification of the respective legal rules, but also their comparison is difficult, since the interpretation of these vague and more general laws is left to the stakeholders, law enforcement agencies, and finally to the judiciary. Since in this latter group of countries however relevant judicial cases are very rare, the interpretation of the codes and other comprehensive laws happens on an ad hoc basis, and remains invisible. The differing legal and ethical issues concerning patients' data in the classical context, and suspects', convicts', victims' and other persons' data protection in a forensic context will be addressed in light of the 2003 International Declaration on Human Genetic Data. Actual examples from Central European jurisdictions will highlight the related theoretical and practical problems both in terms of bioethical research and forensic sciences on the one hand and data protection and privacy on the other.

Key words: Biobanks, genebanks, data protection, forensic genetics, Central and Eastern Europe

* Correspondence address: Dr. Petra Bárd, LL.M. SJD, Central European University's (CEU), Center for Ethics and Law in Biomedicine, Nador u. 9., H-1051 Budapest, Hungary, Phone: +3614723404; Fax: +3613283410; e-mail: bardp@ceu.hu (Homepage: http://www.celab.hu/).

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1. Introduction

In the present paper I will discuss the existing regulatory framework of biobanks across the European Union focusing on the collection and analysis of legislation and regulation regarding the establishment, management and functioning of classical, population and forensic biobanks across Europe focusing on Central Eastern European Member States.

It is worth considering the international instruments applicable and binding even in lack of national regulation of the matter, as there is a great diversity as to biobank laws and related legislation across Europe. Moreover many countries do not have any biobank laws, and in a number of Central Eastern European states one has to rely on laws of diverse nature that serve as background pieces of legislation applicable to biobanks. These laws may include acts, statues or other pieces of legislation on health care, data protection, privacy, patients' rights, medical research, or even comprehensive codes, such as the Civil Code or the Criminal Code. Since in the majority of the Member States there is no specific law with a matching title, it is often a problem for biologists, doctors or even ethicists to identify the proper documents. Even if the laws are identified, the relevant parts have to be found and the often too general provisions need to be applied to the specific case of biobanks.

Before going into the merits and discussing the international and domestic pieces of legislation applicable to biobanks, there is a preliminary issue to be clarified: how we define, what we exactly understand under the term biobank. The issue of biobanks and the legal and ethical considerations surrounding them are rather novel, therefore it should not come as a surprise that there is no widely recognized international definition. As a natural consequence domestic jurisdictions greatly differ in the definition and regulation of biobanks. In the lack of a common denominator, all divisions seem to be arbitrary and therefore should be treated carefully and in a flexible manner.

One may differentiate population biobanks receiving supplies in an organized manner, containing biological materials and personal data and established to supply biological materials or data derived therefrom for multiple future research projects from research biobanks developed by and restricted to authorized clinical investigations at academic medical centers. These databases contain genetics and other biomedical information about connecting individual patients derived from their clinically collected tissues, with the electronic data sometimes being transmitted to a central database. Although sometimes discussed jointly with classical biobanking, forensic databases greatly differ in nature from the above classical and population biobanks. In the broad sense forensic databases are DNA databanks held by authorized laborato-

ries of police and official forensic institutions for criminal and other legal procedures, such as the identification of victims, missing persons, perpetrators, the establishment or rejection of paternity, etc. There is a qualitative difference in the legal sense between the classical and population biobanks on the one hand, and forensic biobanks on the other.[1] The former group invokes questions such as whether the collection or storage of data are free, or whether donors are remunerated, whether consent is needed and what amounts to informed consent, or the way withdrawal happens. These questions do not make sense in the context of forensic databanks, where the question much rather is whether coercion can be used for data collection, and whether tissues, cells and connected data are destroyed once the purpose of the collection (identification of perpetrator, identification of victims, etc.) are fulfilled.

In the following the division between population and classical biobanks on the one hand, and forensic databanks on the other will be maintained, as they raise entirely distinct legal issues. In Part 2 the former group of biobanks will be addressed starting with international legal sources and then going into the Central European specificities,, while in Part 3 the specific and distinct legal issues concerning forensic databanks will be discussed. In relation to both types of genetic databanks recommendations follow the legal analysis.

2. Classical biobanks

International legal sources

When mapping relevant international legal sources it is worth starting with the UNESCO documents. UNESCO has adopted three declarations concerning bioethics, the Universal Declaration of Human Genome and Human Rights (1997), the International Declaration on Human Genetic Data (2003) and the Universal Declaration on Bioethics and Human Rights (2005).

The »Convention on Human Rights and Biomedicine« opened for signature in April 1997 is known as the Oviedo Convention. It came into force in December 1999 and was ratified by 34 Member States in February 2009. This is the first and only binding instrument that explicitly links human rights and bioethics. On several occasions the **European Court of Human Rights** has based legal decisions on

[1] In most of the jurisdictions samples are only stored from unresolved crimes or crime scenes, and suspects' or convicts' samples are destroyed once the profile has been derived therefrom. Therefore forensic biobanks typically contain less samples than genetic profiles, if any, and accordingly a legitimate debate evolved as to whether they may be called genebanks or not. Keeping this debate in mind, and acknowledging its relevance I would like to stress that in the present paper the phrase »forensic biobank« refers to both databanks including samples and profiles, and also repositories only including one or the other.

the Oviedo Convention, including cases where the states had not ratified, or even signed the Convention.

Four Additional Protocols have been adopted on the following topics: the Prohibition of Cloning Human Beings (1998), the Transplantation of Organs and Tissues of Human Origin (2002), Biomedical Research (2005) and Genetic Testing for Health Purposes (2008).

Perhaps the most specific among all the texts adopted within the Council of Europe is the Recommendation (2006) 4 of the Committee of Ministers to Member States on research on biological materials of human origin. In its Preamble the Recommendation states that »population biobanks developed on the basis of donations of biological materials made in a spirit of solidarity should not be monopolized by small groups of researchers.« The Recommendation provides basic rules for obtaining biological materials, access to and oversight of biobanks. Article 4 promotes the establishment of codes of good practice to ensure compliance with this Recommendation.

As a background legislation the comprehensive Convention for the Protection of Human Rights and Fundamental Freedoms shall also be mentioned.

In addition to legal sources numerous professional bodies adopted in the field of biobanks.[2]

Among the primary sources of European Union law, the Charter of Fundamental Rights of the European Union of 2000 is to be mentioned. The Charter can be regarded as the Bill of Rights of the European Union, but opposed to most national constitutions listing fundamental rights, it is a novel document, therefore it is rather progressive. Article 1 on human dignity, and more specifically Article 3 on the right to the integrity of the person are of great relevance.

[2] The European Science Foundation extensively dealt with and formulated recommendations for »Population Surveys and Biobanking« in its May 2008 Science Policy Briefing.
In 2004, a group of experts including those working in the fields of human genetics, sociologists, university researchers, the industry, patient organisations and the European Parliament published a report commissioned by the European Commission with 25 recommendations on ethical, legal and social aspects of genetic testing. Among these, six focused on biobanks and issues related to research.
In 2001, the European Society of Human Genetics (ESHG) published a background document discussing technical, social and ethical issues and a set of recommendations concerning data storage and DNA banking for biomedical research.
The OECD Working Party on Biotechnology was developing Council Guidelines on human biobanks and genetic research databases through an expert group of member countries. A background document with the title »Creation and Governance of Human Genetic Research Databases« came out already in October 2006.
An early document of the Human Genome Organization is also noteworthy. The HUGO Ethics Committee published a Statement on DNA Sampling: Control and Access already back in February 1998.

As to the sources of secondary legislation, the following documents are relevant: Regulation 45/2001 on the protection of individuals with regard to the processing of personal data by the Community institutions and bodies and on the free movement of such data, Directive 2006/86/EC implementing Directive 2004/23/EC as regards traceability requirements, notification of serious adverse reactions and events and certain technical requirements for the coding, processing, preservation, storage and distribution of human tissues and cells, Directive 2006/17/EC implementing Directive 2004/23/EC as regards certain technical requirements for the donation, procurement and testing of human tissues and cells, Directive 2005/62/EC implementing Directive 2002/98/EC as regards Community standards and specifications relating to a quality system for blood establishments, Directive 2005/61/EC implementing Directive 2002/98/EC as regards traceability requirements and notification of serious adverse reactions and events, Directive 2004/33/EC of 22 March 2004 implementing Directive 2002/98/EC as regards certain technical requirements for blood and blood components, Directive 2004/23/EC on setting standards of quality and safety for the donation, procurement, testing, processing, storage and distribution of human tissues and cells, Directive 2002/98/EC setting standards of quality and safety for the collection, testing, processing, storage and distribution of human blood and blood components and amending Directive 2001/83/EC, Directive 2001/20/EC on the approximation of the laws, regulations and administrative provisions of the Member States relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use, Directive 98/44/EC on the legal protection of biotechnological inventions, and finally Directive 95/46/EC on the protection of individuals with regard to the processing of personal data and on the free movement of such data.

The European Group on Ethics in Science and New Technologies (EGE) is also highly authoritative in questions related to biobanking. Almost all of its opinion are to be taken into account, just to name a few Opinion n°19 on the ethical aspects of umbilical cord blood banking, Opinion n°15 on ethical aspects of human stem cell research and use, and Opinion n°11 on the ethical aspects of human tissue banking are of great relevance. The Article 29 Data Protection Working Party adopted a Working Document on Genetic Data on 17 March 2004.

Mapping biobanks in CEE

Biobanks are nationally regulated, through a combination of general and specific laws and oversight bodies. The laws differ greatly from one another, their scopes greatly vary and extend from small scale sample collections to large population

based databases. The confusion between data and sample frequently result in the duality of legal norms; while the collection, storage of biological samples are governed by laws on biomedicine, the data derived from the samples are subject of the data protection law. Even legal experts in the field seem to be ambiguous about the applicability of other legal norms such as law on biomedical research, organ and tissue transplantation, law on genetics, legal norms on patients' rights and on data protection. Most institutions have no written policies or agreements regarding this activity, and even if there was a willingness on the side of hospitals, clinics and research institutes to adjust their practice to some general norms, researchers or drafters of these internal guidelines are in an extremely difficult position due to the large number of international, national, and professional guidelines that contain different, sometimes even contradicting recommendations relevant for biobanks.

Probably the most crucial legal issues to be clarified are data protection and anonymization. Many important contemporary biobanks use a form of reversible anonymisation, or – with another terminology – pseudonymisation, because this is a way to assure protection while keeping a link to be able to update information and to re-contact participants whenever information valuable to the donors is discovered. This is the only way to ensure feedback which is a fundamental reason for many donors to participate in genetic research. The next logical step is to determine what kinds of pseudonymisation techniques are adequate: double coding, single coding or some other method. Even if one named a certain technique, a lack of consensus on the definition prevents researchers from agreeing on standardisation. Professor Bernice Elger proved the varied nature of the many terms. In the tower of Babel of terms – as she called it – one can find references to samples that are anonymous, anonymised, anonymously coded, coded, unidentified, de-linked, permanently de-linked, not traceable, unlinked, identifiably linked, pseudonomised, encoded, encrypted, directly identified, confidential, identifiable, not traceable, or in the UNESCO terminology: linked to an identifiable person. Different legal families adhere to distinct legal traditions, and prefer one or another term over others for legal historical reasons. Sometimes even the same term is used with a different meaning, like the words »anonymised« and »coded« which are filled with different content in Continental and common law jurisdictions.[3]

Putting these terminological discrepancies apart, the main controversy is evolved around the question how to assure adequate anonymisation – be it linked or unlinked. This issue can be subdivided into different narrower questions, like in which form should samples/DNA be stored, used, who shall decide which degree of ano-

[3] Bernice Elger's presentation at the Tiss.EU Workshop organized by CELAB between 6-8 April, 2009 in Budapest at the Central European University.

nymisation is adequate, how many characteristics must be stripped to obtain truly irreversible or reversible anonymisation, and what are the standards for technical questions of security.

Apart from data protection and anonymisation, the issue of informed consent is a fundamental problem to be addressed in an ideal biobank-related legislation. Both the Nuremberg Code and the Declaration of Helsinki incorporate the principle of informed consent as a pillar in the practice of bioethics. Informed consent allows individuals to exercise their fundamental right to decide whether, and how, their body, body parts and associated data can be used in research. The principle of informed consent is applicable for any research on human beings or on human material and as it follows even in the lack of specific legal norm it should be applicable in the field of biobanks as well. As biobank projects are costly and often envisage the multiple use of the samples biobank operators are inventive as to the consent models. One consent type proposed by the Human Genome Organisation in 1998, namely presumed consent, is clearly favoured less often than the others. Estonia applies the so-called open consent model, which does not specify the research in which samples and data are used and applies a general consent form. This model may be corrected with the conditional consent model (in which a person may exclude in advance certain types of research use).

One of the most debated issues concerning the legal framework of biobanks are the property rights. These are often not mentioned at all in biobank law even if ownership of samples constitutes a key question in biobanks with serious implications on commercialization. While the Convention on Human Rights and Biomedicine of the Council of states that the human body and its parts shall not give rise to financial gain, this provision seems not to cover the data derived from the physical samples, although in practice data may be of even higher commercial asset than the samples themselves. At least two issues must be addressed regarding property. The first is the individuals' rights concerning their own biological material. The second is the nature of collaboration between academic researchers and private companies in the development of biobank research. Here, the question of ownership of the collections and intellectual property rights need to be addressed.

Professor Judit Sándor identified the good legal practices of classical and population biobank laws in the following.[4]

[4] GeneBanC internal documents (manuscript on file with the author).

1. The process should start with the clear definition of the goal whether the law should cover population based public and private biobanks or certain disease specific ones.
2. The law should include clear arrangement for data processing. Problematic points include the following: anonym data is different from coded data, coded-double coded, genetic sample, specimen, data, linking-cross-linking, transfer.
3. Certain hospitals, universities, research institutes (or their departments) have a sample collection and have stored cells and tissues, but the legislative or a supervisory authority does not have any knowledge about it. It is therefore crucial to make these biobanks transparent with a corresponding obligatory registration system.
4. Researchers in the biobanks are often unaware of the existing background legislation, such as acts, statutes or lower pieces of legislation related to data protection, rules on research. Often the establishment of the biobank has not been preceded by a legal ethical screening and evaluation of the future operation of the institution. Mainly those researchers have an idea about the desirable way of collection, storage and process of data who participate in international, mainly European Union-wide consortia.
5. Identification of rights and interests of research participants, researchers and biotech industry is needed: dignity-privacy-liberty; right to be informed, right to decide (consent); freedom of choice right to withdraw sample/data; short term goals; long term goals (freedom of research); biobanks are often seen as investment in the future it poses legal challenges: validity of the consent, access to old collections, follow up procedure is still necessary
6. It would be crucial to develop mechanisms for biobank monitoring.
7. The law on new technologies often require further adjustment, corrections, therefore adequate follow up mechanisms are desired.

3. Forensic databanks

International legal sources

From among the three main UNESCO Declarations mentioned above, the second one, the International Declaration on Human Genetic Data of 2003 might be of relevance. The main focus of the document however is not on the forensic use of genetic information, but primarily on genetic research, the sequencing of the human genome, and its medical research and biomedical applications.

Beside the Convention for the Protection of Human Rights and Fundamental Freedoms and the related case-law of the European court of Human Rights,[5] 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. 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 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 that 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. Rehabilitation is an important aspect of criminal policy. Should data of perpetrators remain in a forensic database for disproportionately long periods of time,

[5] *Leander v. Sweden* of 26 March 1987, Application no. 9248/81, *Al-Nashif v. Bulgaria* of 20 June 2002, Application no. 50963/99, *Lupsa v. Romania* of 8 June 2006, Application no. 10337/04, *Puig Panella c. Espagne* de 25 avril 2006, Requête no 1483/02

especially if entities other than law enforcement agencies have access to these databanks, the objective of rehabilitation cannot be fulfilled. Both the Committee of Minsters Recommendation No. R (84) 10 on the criminal record and rehabilitation of convicted persons[6] and Recommendation No. R (96) 8 on crime policy in Europe in a time of change are putting emphasis on the aim of rehabilitation.

Although reference has already been to the case-law related to the European Convention on Human Rights, one particular decision, S. and Marper v. the United Kingdom[7] is worth of mention in greater detail. In this case the European Court of Human Rights held in a unanimous decision that the United Kingdom was in violation of Article 8 of the European Convention on Human Rights, when the UK authorities continued to retain the Applicants' fingerprints, DNA samples and profiles after criminal proceedings against them had ended with an acquittal or had been discontinued. The ECtHR adhered to its own case law when underlining that 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.[8] According to the Court 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. 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. In the Court's view the UK law 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 Court however did not stop the examina-

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[6] Also incorporated into Recital (10) of Council Decision 2005/876/JHA of 21 November 2005 on the exchange of information extracted from the criminal record: »Under Council of Europe Recommendation No R (84) 10 on the criminal record and rehabilitation of convicted persons, the main aim of establishment of the criminal record is to inform the authorities responsible for the criminal justice system of the background of a person subject to legal proceedings with a view to adapting the decision to be taken to the individual situation. Since all other use of the criminal record that might compromise the chances of social rehabilitation of the convicted person must be as limited as possible, the use of information transmitted under this Decision for use otherwise than in the course of criminal proceedings can be limited in accordance with the national legislation of the requested State and the requesting State.«

[7] *S. and Marper v. the United Kingdom* of 4 December 2008, Application numbers 30562/04 and 30566/04.

[8] *Leander v. Sweden* of 26 March 1987, Application number 9248/81, *Amman v. Switzerland* of 16 February 2000, Application number 27798/95

tion at this point, but noted that all the 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 agreed with the UK Government 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. 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. 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 who was 11 at the time his samples were taken. 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 over-representation of young persons and ethnic minorities in the biobank.

The case is interesting so much the more as several Member States seem to be in violation of Article 8 as interpreted by the ruling of the Court. Details will follow in Part 7.

As it has already been proven the European Union proved to be a promoter of the exchange of law enforcement information. A novel, fifth freedom seems to be added to the free movements of goods, capital, services, and persons forming the basis of the internal market of the European Union. Already 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 (Data Protection Directive) mentioned in its title the addition to the four freedoms. Since the adoption of the Data Protection Directive the free movement of data gained increased importance among others in the third pillar. Examples are Council Framework Decision 2006/960/JHA on simplifying the exchange of information and information and intelligence between law enforcement authorities of the Member States of the European Union, or more specifically in the area of exchange of DNA information the Prüm Framework Decision 2008/615/JHA on the stepping up of cross-border cooperation, par-

ticularly in combating terrorism and cross-border crime and the implementing Council Decision 2008/616/JHA.

According to the former, Member States ensure that any type of information or data which is held by law enforcement authorities or by public authorities or by private entities and which is available to law enforcement authorities without the taking of coercive measures are exchanged among Member States' law enforcement authorities for the purpose of conducting criminal investigations or criminal intelligence operations. The latter two instruments also contain provisions that make the exchange of information less burdensome on the conditions and procedure for the automated transfer of DNA profiles, dactyloscopic data and national vehicle registration data.

The question than is what measures would balance the free flow of sensitive information from a human rights perspective.

In the framework of the European Union, the Data Protection Directive might seem 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 Data Protection Directive however is a first pillar instrument and therefore its scope does not extend to criminal cases or criminal cooperation. In both Recital (13) and Article 3 (2) on the scope of the Directive it is clearly stated that Titles V and VI TEU on public safety, defence, state security, national criminal law all fall outside the scope of the Directive.

The question then arises whether the recently adopted 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 (Framework Decision on Data Protection) applies to forensic biobanks.

Unfortunately the scope of the Framework Decision itself is rather limited. Both according to Recital (7) and Article 1 (2) there has to be a European element for the Framework Decision to apply.

The Framework Decision entered into force in January 2009, on the 20th day following its publication in the Official Journal of the European Union, and Member States have to take the necessary measures to comply with the provisions of the law until 27 November 2010.

Mapping forensic databanks in CEE and beyond

The purposes of a forensic databank may vary from prosecution and the identification of perpetrators to the identification of victims, the identification of victims in mass disasters (e.g. air crash or natural catastrophe victims),[9] or conducting familial searching or paternity tests.[10] The development of forensic genetics, especially the fact that genetic material can now be derived from small amount of samples, also enables the reopening of old so-called »cold cases«. Not only do these databases contribute to the finding of perpetrators, but may also clear convicts.[11]

Digitalized DNA profiles enable the tracing of suspects, the identification of victims, and sometimes also missing persons. The digitalized profiles are a sufficient means to achieve these aims, however beside the profiles samples are also stored for a number of purposes, such as retesting, quality control, submission to updated technology, etc.

Samples include skin cells, hair, blood, saliva, buccal swab, semen, etc. They are typically frozen at low temperatures (for example in case of blood banks -80 ˚C), other sampling techniques allow storage at room temperature.[12]

Data include the DNA profiles on the one hand, and on the other a number of personal data, depending on the jurisdiction. These latter may include name, maiden name, mother's maiden name, place and date of birth, address, sex, in some countries physical appearance, ethnic origin, the person and/or the laboratory who/where the sample has been taken, the type and method of testing, etc.

Current research enables forensic experts to derive profiles from very small samples. Once a match is found this does not automatically serve as conclusive evidence of guilt, first because a match does not prove but only that someone was present at a crime scene, and second due to the fact that forensic experts can only tell the prob-

[9] Andrea Piccinini, Ferruccio Betti, M. Capra, Cristina Cattaneo, The identification of the victims of the Linate air crash by DNA analysis, in *Progress in Forensic Genetics* 10, Amsterdam: Elsevier, 2004, 39-41; T. Bille, R. Wingrove, M. Holland, C. Holland, C. Cave, J. Schumm and The Staff of The Bode Technology Group, Novel method of DNA extraction from bones assisted DNA identification of World Trade Center victims, in *Progress in Forensic Genetics* 10, Amsterdam: Elsevier, 2004, 553; Martin Steinlechner, Walther Parson, Walter Rabl, Petra Grubwieser and Richard Scheithauer, Tsunami-disaster: DNA typing of Sri Lanka victim samples and related AM matching procedures, in *Progress in Forensic Genetics 11 - Proceedings of the 21st International ISFG Congress held in Ponta Delgada, The Azores, Portugal between 13 and 16 September 2005*, Amsterdam: Elsevier, 2006, 741-743.

[10] In the present analysis the focus is on forensic databanks established for crime prevention and prosecution purposes, therefore identification of mass catastrophe victims or the establishment of paternity falls outside the scope of the paper.

[11] In the US Innocent project 238 convicted persons have proved to be innocent on the basis of the technique of forensic genetics. http://innocentproject.org/

[12] Robert F. Weir and Robert S. Olick, The stored tissue issue, Oxford: Oxford University Press, 2004, 79.

ability that a certain DNA profile belongs to a given individual. Third, there is the possibility of human error, as always.

In theory it would be sufficient to store the profiles derived from DNA electronically, and not keeping the samples. National data protection rules however do not seem to regulate this: even the data protection rules seem to apply to the profiles, and not to the samples.[13] In the lack of a common regulation, Member States' regulations greatly differ on this matter as well. Belgium, Germany, Lithuania, Sweden destroy the samples once the DNA profiles have been created, while in Hungary or Malta the period for which samples are stored depends on the crime committed by the convict, whereas in some Member States like in the UK samples are stored indefinitely. As to the DNA profiles, many more Member States allow indefinite retention, which seems to be disproportionate in light of the above Marper decision of the European Court of Human Rights.

A forensic DNA typically contains crime scene samples, samples and profiles of convicts and suspects, sometimes also of victims, volunteers, or missing persons. Crime scene samples are the least problematic ones from the point of view of bodily integrity, as the retention of such samples does not necessitate invasion into the body, however minor. As to suspects and convicts the case is rather different. As opposed to classical medical or population biobanks, persons suspected of having committed certain crimes are typically not free to opt not to have their samples taken. Sample taking is intrusion into spatial privacy or bodily integrity, however minor (like in case of buccal swab, or saliva) and in the majority of the Member States even coercion may be used to acquire samples.

In medical research, i.e. in case of classical biobanking this problem is solved by informed consent, i.e. persons whose samples enter a database agree to sample taking and data retention and processing with the possibility of withdrawal any time, without any reason. As a compensation for the lack of consent and the fact that force may be used against people who are supposed to be presumed innocent, in some Member States a court order or the permission of high ranked policepersons needs to be acquired.

In most of the jurisdictions there is a list of crimes or types of crimes the perpetrators of which are obliged to give samples. Other states argue that those committing serious crimes had already committed minor ones, therefore it is advisable to expand the list of offences. Germany took a more balanced approach and perpetrators committing minor offences are only obliged to give samples if they are recidivists.

[13] Nathan Van Camp and Kris Dierickx, »National Forensic DNA Databases – Socio-Ethical Challenges and Current Practices in the EU,« *European Ethical-Legal Papers* No 9, Leuven, 2007, 25.

A further distinction shall be made between those suspected and those sentenced. Persons suspected against whom charges have been dropped or whose criminal liability has not been established in a judicial process under due process shall be presumed to be innocent. Retaining their data therefore is highly problematic, stigmatizing them, and if we consider that disproportionately more charges are taken and dropped in case of certain minority groups,[14] their discrimination will be reinforced by their overrepresentation in the forensic database.

At the same time some problems may arise also in relation to sample taking from convicts. If we accept that the sole aim of a forensic databank is the identification of persons who had committed crimes, the question arises why to take the sample from convicts already found and proven to be guilty. The only objective – beside the very technical consideration of checking the system and its upgrades – must then be to catch these individuals more efficiently if they commit further crimes. In this case however it needs to be proven that convicts are likely to engage in criminal activity after the perpetration of the first committed crimes as well. When relying on statistical findings it is worth differentiating between first offenders and recidivists, as their recidivism rates may be different. Even if a correlation can be found between first and second or multiple offending, after a certain period the likelihood that someone engages in further crimes, diminishes. Since criminal activity is typical for a certain age range, it might seem disproportionate keep data and/or samples of people who have once been convicted for decades. This is especially true for minor crimes.

A forensic database may also have the severe side effect of hitting disproportionately hard on persons belonging to a certain underrepresented ethnic origin or to a given social class – characteristics that may be searched for and indicated in the UK's NDNAD. Searching for close matches to information derived from a crime scene sample may result in the finding of relatives of perpetrators. Such familial searching however is highly problematic, as biologically related persons to perpetrators – in some jurisdiction including minors – become automatically suspect, eventually stigmatised. It is to be noted that the age of culpability is different in the EU's Member States, and in the UK for example the age of criminal liability, i.e. the age limit for entering someone's data into the NDNAD is 10 years.

Children and other vulnerable groups are typically granted higher protection in case of medical genetic research and data sampling or storage; in some cases retention of

[14] E.g. in the male population of the United States of America 92 % of African Americans prove to be innocent as compared to the 62 % in case of Caucasian American citizens; in the European context almost two third of samples stored in the NDNAD belong to black men as opposed to 8 % of the samples taken from white men. Mairi Levitt, Forensic databases: benefits and ethical social costs, 83 *British Medical Bulletin* 1, 235-248 (2007), 242

data is entirely impermissible. As the Romanian Constitutional Court held in a recent decision,[15] the fact that samples are taken from persons between 14-18 years of age, i.e. from persons culpable, but still minors with the meaning of the Children's Rights Convention is not per se unconstitutional. However, at the international level, the United Nations Guidelines for the Prevention of Juvenile Delinquency warn against labelling and stigmatising a young person as »deviant,« »delinquent« or »predelinquent.«[16] Nevertheless in the NDNAD alone there were in 2006 40.000 people under 18 years of age who have never committed a crime.[17] There is no reason to disregard the need for greater safeguards in the criminal context, which raises eventually equally or more serious concerns as to human rights, since highly sensitive and possibly stigmatising data that may also distort the relation between the state and the individual, and that may result in self-fulfilling prophecies, are involved.

Based on the finding of our research, the following good practices may be formulated in the regulation of forensic databases.

1. The objectives of the forensic biobanks shall be clearly regulated. The branch of law to regulate the issue of forensic databases shall be clarified. Different purposes shall be regulated by laws belonging to different branches of law, and these rules shall be clearly separated.
2. Samples and profiles shall be clearly distinguished. Different rules shall apply to the storage of samples and profiles. They shall satisfy the requirements as laid down in binding international instruments and in the soft laws. Most importantly storage shall satisfy the test developed by the European court of Human Rights.
3. Sample taking shall be safeguarded by human rights guarantees. We do acknowledge that the requirement of consent is impracticable in the criminal context, but as a compensation preferably a judicial decision hall be needed for sample taking.
4. The purpose of the law – especially in the criminal context – shall be clearly defined. Should the main purpose be identification of perpetrators, the legislative has to give reasons as to why to take the samples from convicts after they have already been convicted – a practice in many jurisdictions.

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[15] Decision No. 485/2009 on the constitutionality of Article 5 Section (3) of the Law No. 76/2008 on the Organizing and Functioning of the National Judicial Genetic Data System

[16] FN 25 in Mairi Levitt, Forensic databases: benefits and ethical social costs, 83 *British Medical Bulletin* 1, 235-248 (2007)

[17] The DNA database and you, http://rinf.com/alt-news/surveillance-big-brother/the-dna-database-and-you/4820/

5. The list of crimes for which samples are to be taken shall be laid down by law. Preferably only perpetrators or suspects of the more severe crimes shall be subjected to sample taking, or recidivists. Whenever irrelevant, like in economic crimes, sample taking shall not be required.

6. Samples and profiles shall be stored for definite periods. We do acknowledge that the deletion of samples is impracticable, since it is essential to have samples available for retesting in case the tests or their methods are being disputed in a case, further quality control necessitates their storage, and finally, as technology develops, samples may be submitted to retesting again and again, and it may be impractical to recreate the database each time a new technological method has been invented. Nevertheless since they contain information irrelevant for identification purposes they shall preferably deleted once the profiles are derived therefrom or when a final decision has been rendered in the given case.

7. There shall be deadlines for the deletion of the profiles as well. These shall depend on the gravity of the crime. Samples and profiles of persons not found guilty shall be immediately destroyed and deleted respectively.

8. The scope of persons having access to samples and profiles shall be laid down by law.

9. Data transfer shall happen through secured means.

10. Sample taking, storage and erasure shall be monitored.

11. Forensic databased must never be interconnected with other databases, and especially not with population or classical biobanks.

12. Special regard shall be given to the right of children and other vulnerable groups.

13. A right to judicial remedy against sample and profile storage shall be guaranteed.

14. Unification of data protection standards across Europe would be the *sine qua non* of criminal cooperation. Without sufficient and uniform human rights mechanism the transfer of profiles remains highly problematic.