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JUDIT SÁNDOR
PETRA BÁRD

THE LEGAL REGULATION
OF BIOBANKS

National Report: Estonia



CENTER FOR ETHICS AND LAW
IN BIOMEDICINE





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THE REGULATORY FRAMEWORK OF THE ESTABLISHMENT, MANAGEMENT AND FUNCTIONING OF BIOBANKS IN ESTONIA

As partners in the European Union Framework Project entitled “GeneBanC: Genetic bio and dataBanking: Confidentiality and protection of data” we are exploring the legal regulations of databanks. (<http://www.genebanc.eu/>) The Center for Ethics and Law in Biomedicine established at the Central European University, Budapest (<http://www.ceu.hu/celab>) aimed to investigate the existing regulatory framework of biobanks across the EU and focus on the collection and analysis of legislation and regulation regarding the establishment, management and functioning of classical, population and forensic biobanks across Europe. An important objective was to look at the similarities and differences in such legislation and regulations, in order to formulate recommendations towards a harmonization of European practices and regulations. The European jurisdiction was divided up into two parts between CELAB and the Belgian project partner, the

Centre for Biomedical Ethics and Law, K.U.Leuven. CELAB was focusing on the regulatory framework of Cyprus, the Czech Republic, Estonia, Greece, Hungary, Italy, Latvia, Lithuania, Malta, Poland, Romania, the Slovak Republic, and Slovenia. The present booklet is the first one in the series of country reports prepared by CELAB.

In order to familiarize ourselves with the situation how biobanks actually work we have launched a questionnaire about the legal framework and we received substantial help from a number of scholars. We would like to express our gratitude for their useful comments and substantial help to Dr. Anu Aaspõllu from the Forensic Service Centre and to Dr. Ants Nõmper, senior lecturer at the University of Tartu. Prior to the beginning of this project we visited the headquarter of the Estonian Genome Project in Tartu.

Budapest, 31 July 2009

I. CLASSICAL AND POPULATION BIOBANKS

1. THE ESTONIAN GENOME PROJECT

The idea of a nation-wide genetic database – as well as the notion of the Estonian Genome Project¹ (EGP) – was based on the recommendation of scientist and professionals in the field of biotechnology. The initiators presented their proposal to the Estonian Government in 1999 with the aim of creating a database of health, genealogy and genome data that would entail genetic data (consisting of phenotype and genotype data) of the majority of the Estonian population. The database should enable research into links between genes, environmental factors and common diseases (such as cancer, diabetes, depression, cardio-vascular diseases etc.) and make it possible to apply the information gained from research to making new discoveries in genomics and epidemiology, which, in turn, might lead to increasing efficiency of health care.² The idea of establishing a national gene bank has reached the Estonian public agenda in the fall of 1999 when Andres Metspalu, a profes-

sor of biotechnology at the University of Tartu and currently acting as head of the EGP and other scientist gave interviews on their intention to launch the project.³

One of the most well-known and significant example of biobank-related projects in the Central-European region is the Estonian Human Genome Project which was initiated just after the establishment of a private foundation, the Estonian Genome Project Foundation⁴ (EGPF or Foundation) which was founded in 2001 by Estonian scientists, doctors and politicians to support genetic research and biotechnology in Estonia. The EGPF is a quasi-autonomous non-governmental organisation and belongs formally to the Ministry of Social Affairs. Setting up the database as a foundation, in a framework of a non-governmental organization seemed to enable the involvement of private funding without many regulatory problems. Nevertheless from an institutional perspective, the foundation has not been related to the EGP directly rather it has created a common platform for coordi-

¹ In original language: *Eesti Geenivaramu*

² Further details are available at the website of the Estonian Human Genome Foundation: <http://www.genomics.ee/index.php?lang=eng&show=20>

³ Further information is also available at the website of the Estonian Genome Foundation: <http://www.genomics.ee/files/menu/egp.pdf>

⁴ In original language: *Sihtasutus Eesti Geenikeskus*. Further information is available on the Estonian Genome Foundation at the website of the organization: <http://www.genomics.ee/index.php?lang=eng>

nating the activities of different interest groups.⁵

With the aim of establishing the necessary institutional and organizational framework for the EGP the Estonian government adopted the Human Genes Research Act⁶ (HGRA) in December 2000 which entered into force at the beginning of 2001. The Human Genes Research Act represents one of the first attempts to establish legislative framework and codify law in the genetic era, and it has already served as a model for other countries intending to launch their own genome projects.⁷ The Act was prepared by an international working group and guidance was obtained from the available relevant international pieces of legislations dealing with genetic research, such as the UNESCO Universal Declaration on the Human Genome and Human Rights⁸ and the Oviedo Convention on Human Rights and Biomedicine.⁹

According to the website of the Foundation it was also agreed that the EGP must be carried out with governmental support to a certain extent and regarding a set of principles based on the European consensus to avoid frag-

mentation of social solidarity and ensure the public acceptability and respectability of the project.¹⁰ The public funding of the project however, remained symbolic until 2007 and in 2001 the EGPF founded a private company EGeen Ltd (having its registered seat in Estonia) to finance and also commercialize the results of the EGP. According to the contract signed on 19 September 2001, EGeen Ltd obtained the commercialization rights of scientific results made in the framework of the EGP for 25 years. In addition to the above the EGeen Ltd was obliged to make the annual payment of about 300 thousand Euros to the Foundation and there were also additional payments depending on the financial success: unlimited annual profit payment of 0.5%, and 3% of the turnover. The EGeen Ltd., in turn was founded by a US-based, Delaware private company called EGeen International Inc., which pooled funding from different venture capital firms (mostly international) and private individuals (mostly Estonians).¹¹

The Estonian Genome Project was launched in September 2002 and the first part of the project was successfully completed at the beginning of 2003.

⁵ See Kattel, Rainer and Suurna, Margit: *The Rise and Fall of the Estonian Genome Project. Innovation in Central and Eastern Europe*, Volume 2, Issue 2 2008 Article 4. p. 6. The Berkeley Electronic Press.

⁶ Human Genes Research Act passed by the Riigikogu on December 13, 2000 (as RT I 2000, 104, 685), entered into force on January 8, 2001. RT is Riigi Teataja (State Gazette). In original language: Inimgeeniuringute seadus. Official English translation is available at: <http://www.legaltext.ee/text/en/X50010.htm>

⁷ Ants Nõmper, Krista Kruuv. *The Estonian Genome Project. – Society and Genetic Information*. In: Judit Sándor (ed.), *Codes and Laws in the Genetic Era*, Budapest: CEU Press, 2003, p. 213–225

⁸ Universal Declaration on the Human Genome and Human Rights 11 November 1997, available at: http://portal.unesco.org/en/ev.php-URL_ID=13177&URL_DO=DO_TOPIC&URL_SECTION=201.html

⁹ Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine (ETS No. 164). Signed in Oviedo, 4. IV. 1997. Available at: <http://conventions.coe.int/treaty/EN/Treaties/Html/164.htm>

¹⁰ Further information is available at: <http://www.genomics.ee/pics/moodulid/egp.gif>

¹¹ Kattel and Suurna 2008, p. 7-8

The principal goal of this pilot phase was testing the technical and organizational readiness for carrying out the main project in three counties of the country. The second stage launched in March 2003 involved the Estonian population from more and more counties into the data collection process with the aim of covering the whole population by the project. In addition to the above, general practitioners, specialists have also started to collect blood samples and medical history records. For the year of 2003, the principal aim was to collect the descriptions of health status and tissue samples of 10,000 gene donors.

In late 2003 conflicts were materialized between the EGP and the EGeen Ltd. according to which the latter started to question the quality of collected data and wanted to concentrate on research of specific disease groups, obvious targets for commercial application.

At the end of 2004, the contract with the main financier EGeen Ltd. and the EGP was terminated which also meant that the EGP was released from the exclusive rights agreements with EGeen Ltd. and that EGeen Ltd. was no longer obliged to finance the activities of the EGP. The database contained by that time samples from around 10,000 gene donors. From 2004 to 2007 a political debate was fuelled over the future of the EGP and activity of the

project was frozen during this period with an emphasis on the maintenance of the previously gathered DNA samples. Nevertheless, during this period the EGP launched a cooperation project with Latvia funded by the European Union about cancer prevention measures in the two countries, throughout which 5,000 additional samples were gathered by the end of 2006.¹²

In 2007 the Estonian Parliament has amended the Human Genes Research Act according to which the EGP will continue as a structural unit of the University of Tartu and is guaranteed public funding amounting to 7.7 million Euros for the years 2007-2009.¹³ The Estonian Genome Project of the University of Tartu carries out the Estonian Genome Project with the goal to create a database (biobank) of health, genealogy and genome data from 100,000 individuals by 2010.

Since its establishment publications on the Estonian Human Genome Project prone to compare it to the Icelandic Genome Project.¹⁴ Although both initiatives have a lot in common, several reasons call for careful and limited comparison between the two projects. Rather than looking for genes that cause disease, as in Iceland, the Estonian project is focusing on how genes influence individual responses to medicines.¹⁵ Additionally unlike the Icelandic database the EGP intended to incorporate genetic information into

¹² Kattel and Suurna 2008 p. 9

¹³ Kattel and Suurna 2008 p. 10

¹⁴ In December of 1998 the parliament of Iceland passed a bill that allowed for the creation of a centralized database of all the Icelandic peoples' genealogical, genetic, and personal medical information. The parliament then granted an exclusive contract to deCODE genetics, a biomedical company, giving deCODE access to the national health records.

¹⁵ Frary, Mark: Estonian genome project ahead of schedule, Estonian Genome Foundation, December 23, 2002. Available at: <http://www.genomics.ee/index.php?lang=eng&nid=125>

medical care by releasing data to individuals and their physicians upon the request of the general practitioner and with the prior consent of the patient (Article 27.4 and 16.2).¹⁶ It is also worth mentioning that the Estonian Genome Project contrary to the Icelandic one, places strong emphasis on the individual rights of the donors.¹⁷

Finally, one of the distinguishing features of the Estonian Gene Bank is that the information in the database can be decoded.¹⁸

2. DEFINITION OF BIOBANKS

Article 2 of the Human Genes Research Act sets out the definition of 'Gene Bank' according to which it "means a database established and maintained by the chief processor¹⁹ consisting of tissue samples, descriptions of DNA, descriptions of state of health, genealogies, genetic data and data enabling the identification of gene donors". On the basis of the same Act the chief

processor of the Gene Bank is a non-profit foundation founded by the Republic of Estonia on the basis of the Participation in Legal Persons in Private Law by the State Act²⁰ within the area of government of the Ministry of Social Affairs which has the right to organise the taking of tissue samples, to prepare descriptions of state of health and genealogies, to code, decode, store, destroy and issue descriptions of state of health and genealogies, to perform genetic research and to collect, store, destroy and issue genetic data.

3. RELEVANT LAWS

The legal framework for the activities of the Estonian Genome Projects consists of the Constitution of the Republic of Estonia,²¹ the aforementioned Human Genes Research Act, the Personal Data Protection Act, the Databases Act and the Council of Europe Convention on Human Rights and Biomedicine. Additionally to the above, after the in-

¹⁶ Ethics and Law of Intellectual Property: Current problems in Politics, Science and Technology. Applied legal philosophy Ed. Christian Lenk, Nils Hoppe, Roberto Andorno. Aldershot, England; Burlington, VT: Ashgate, 2007.

¹⁷ See also Relevant Laws

¹⁸ Nõmper and Kruuv. 2003. For further information on the decoding process see Storage.

¹⁹ Based on the definition in the 2003 version of the Estonian Personal Data Protection Act, "chief processors" are equivalent to "controllers" as it is defined by Article 2 (d) of the European Union Data Protection Directive (1995/46/EC). The Estonian term "authorized processor" is the equivalent of the term "processor" as it is defined by Article 2 (e) of the EU Directive 1995/46/EC. (World Legal Information Institute. EPIC – Privacy and Human Rights Report 2006. Estonia. Available at: <http://www.worldlii.org/int/journals/EPICPrivHR/2006/PHR2006-Republic-8.html#fn2139>)

²⁰ Participation in Legal Persons in Private Law by the State Act Passed 24 March 2004 (RT I 2004, 24, 166), entered into force 16 April 2004. In original language: Riigi eraõiguslikes juriidilistes isikutes osalemise seadus. Official English translation is available at: <http://www.legaltext.ee/en/andmebaas/ava.asp?m=022>

²¹ The Constitution of the Republic of Estonia passed by a referendum held on 28 June 1992 (RT I 1992, 26, 349), entered into force 3 July 1992, (amended by the following Acts: RT I 2007, 33, 210; RT I 2003, 64, 429; RT I 2003, 29, 174.) In original language: Eesti Vabariigi põhiseadus. Official English translation is available at: <http://www.legaltext.ee/en/andmebaas/ava.asp?m=022>

stitutional reorganization of the Project in 2007 the EGP also falls under the scope of University Act.

Article 26 of the Estonian Constitution sets forth that *“Everyone has the right to the inviolability of private and family life. [...]”*. Additionally Article 28 provides that everyone has the right to the protection of health. Article 44 Section (3) of the Constitution also declares that

“an Estonian citizen has the right to access information about himself or herself held in state agencies and local governments and in state and local government archives, pursuant to procedure provided by law. This right may be restricted pursuant to law to protect the rights and freedoms of others or the confidentiality of a child’s filiation, and in the interests of combating a criminal offence, apprehending a criminal offender, or ascertaining the truth in a criminal procedure.”

It also has to be noted that the aforementioned right was only of great importance until 2002, when all the Estonian health service providers (e.g. hospitals) were re-organized as independent legal entities under private law and fell beyond the scope of Article 44 Section (3) of the Constitution.

From the beginning of the Estonian Genome Project, the adoption of a special legislative instrument to regu-

late human gene research and the operation of a Gene Bank have been considered significant for the Estonian legislators. The initiators of the Genome Project set this objective on the basis of their own intention as no national legislation or international obligation exist that provides for the direct requirement for the adoption of such a pieces of legislation,²² however the Convention on Human Rights and Biomedicine of the Council of Europe calls for adoption of necessary legislation to protect the principles laid down in the Convention (as it is set out in Articles 23 and 25).²³ Nevertheless, taking account the broad and soft wording of the Convention it can be stated that the Convention does not burden the obligation to adopt a human genome research act.²⁴

Additionally to the Human Genes Research Act which provides the legal basis of the Estonian Genome Project, five implementing regulations are also considered significant as specific biobank related legislations. The five implementing regulations associated with the HGRA are as follows: (1) Requirements for authorised processors of the Gene Bank (Decree No. 42 of the Estonian Government 2002);²⁵ (2) Format of gene donor’s consent and the procedure for the completion and

²² Nõmper and Kruuv 2003, p. 215-217

²³ See footnote 9

²⁴ Nõmper and Kruuv 2003, p. 215-217. It is also has to be mentioned that the Estonian Human Genes Research Act was adopted more than a year before Estonia ratified the Convention (the Convention on Human Rights and Biomedicine was ratified and entered into force in 2002 in Estonia). Therefore, the adoption of the HGRA with only a few substantial changes (for example, regulation of genetic testing was omitted from the draft Act) reflects a strong sense of responsibility of the initiators of the Estonian Genome Project. See also in: Nõmper and Kruuv 2003, p. 215-217

²⁵ Requirements for authorised processors of the Gene Bank, Decree No. 43 of the Estonian Government. In original language: Geenivaramu volitadu töötlejale estitatavad nõuded. 23.01.2002- RT I 2002, 10, 57.

preservation thereof (Decree No. 125 of the Minister of Social Affairs 2002);²⁶ (3) Procedure for issuing tissue samples, descriptions of DNA and descriptions of health state (Decree No. 126 of the Minister of Social Affairs 2002)²⁷; (4) Conditions for storage of DNA samples, coded descriptions of DNA and coded descriptions of health state (Decree No. 127 of the Minister of Social Affairs 2002);²⁸ (5) Procedure for destroying data which enables decoding, tissue samples, descriptions of DNA and descriptions of health state (Decree No. 128 of the Minister of Social Affairs 2002).²⁹

The Personal Data Protection Act 2003 (PDPA)³⁰ also proves to be important in relation to the protection of data processing for personal data contained in biobanks. Since biobanks contain not only biological samples but also

personal data about the donor of the biological material such as data related to health and genetic data, one of the most significant legal instruments on their regulations is the aforementioned act on data protection which transposed Directive 95/46/EC of the European Parliament and of the Council 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 into national legislation in 2001.

In addition to the above the Databases Act of 1997³¹ addresses a number of issues that are relevant in the context of biobanks. The Databases Act is a procedural law for the establishment of national databases. The law sets out the general principles for the maintenance of databases, prescribes requirements and protection

²⁶ Format of gene donor's consent and the procedure for the completion and preservation thereof, Decree No. 125 of the Minister of Social Affairs. In original language: Geenidoonoriks saamise nõusoleku vorm, selle täitmise ja säilitamise kord. 17.12.2001. - RTL 2002, 1, 6.

²⁷ Procedure for issuing tissue samples, descriptions of DNA and descriptions of state health, Decree No. 126 of the Minister of Social Affairs. In original language: Geenidoonori koeproovi, DNA kirjelduse ja terviseisundi kirjelduse väljastamise kord. 17.12.2001. - RTL 2002, 1, 7.

²⁸ Conditions for storage of DNA samples, coded descriptions of DNA and coded descriptions of state health, Decree No. 127 of the Minister of Social Affairs. In original language: Geenidoonori kodeeritud koeproovi, DNA kirjelduse ja terviseisundi kirjelduse säilitamise tingimused. 17.12.2001. - RTL 2002, 1, 8.

²⁹ Procedure for destroying data which enables decoding, tissue samples, descriptions of DNA and descriptions of state of health. Decree No. 128 of the Minister of Social Affairs. In original language: Geenidoonori koeproovi, DNA kirjelduse, terviseisundi kirjelduse ja tagasikodeerimist võimaldavate andmete hävitamise kord. 17.12.2001. - RTL 2002, 1, 9.

³⁰ Personal Data Protection Act passed by the Parliament of Estonia in February 2003 and entered into force on October 1, 2003. (RT I 2003, 26, 158), amended by the following Act: 14.04.2004 entered into force 01.05.2004 - RT I 2004, 30, 208. In original language: Isikuandmete kaitse seadus. Official English translation is available at: <http://www.legaltext.ee/en/andmebaas/ava.asp?m=022> It is also has to be mentioned that RTI, 16.03.2007, 24, 127 also transposed Directive 95/46/EC into the national legislation. The first legislative instrument that regulates protection of individuals' personal data is Personal Data Protection Act, enacted by the Estonian Parliament in June 1996. The 1996 Act was repealed with the creation of the new PDPA in 2003 to bring it into full compliance with the 1995 EU Data Protection Directive.

³¹ Databases Act of 1997. Passed 12 March 1997 (RT I 1997, 28, 423), entered into force 19 April 1997. Last amendments are made on 08.04.2004 entered into force 28.04.2004 - RT I 2004, 30, 204. In original language: Andmekogude seadus. Official English translation is available at: <http://www.legaltext.ee/en/andmebaas/ava.asp?m=022>

measures for data processing and also mandates the establishment of a state register of databases for state and local government databases, as well as databases containing sensitive personal data maintained by persons in private law.

It is also worthwhile to mention Decree No. 77 (2001) refers to the establishment of research ethics committees.

Concerning the criminal consequences of misdemeanour activities in relation to biobanks, the Criminal Code also considered to be important. Article 124 Section (4) of the Criminal Code declares that inducing persons to become gene donors deems as a punishable offence. The cited provision was transposed into the Criminal Code on 13 December 2000 by RT I 2000, 104, 685 and entered into force on 8 January 2001. Article 124 Section (4) sets forth that inducing persons to consent to providing a tissue sample for the purposes of genetic research by offering material remuneration or by causing damage or threatening to cause damage to the person is punishable by a fine, detention or up to one year imprisonment.

In addition to the above Article 124 Section (5) of the Criminal Code provides that conducting medical or scientific research on a person who has not granted his or her valid consent thereto is punishable by a fine, detention or up to one year imprisonment.

Given the sensitivity of the genetic data collected for biobanks, confidentiality and legally established professional secrecy is considered of great significance. Professionals' confidentiality, including the obligation imposed on medical practitioners is required by the Criminal Code, Article 128 Section (1) of

which sets forth that the *"disclosure by a doctor, medical assistant, nurse, midwife, psychologist, advocate, notary or other person of confidential data relating to the descent, genetic data, artificial insemination, family or health of a person which become known to the offender due to his or her professional activity, if such disclosure violates legislation regulating the professional activity or other legislation, is punishable by a fine or deprivation of the right of employment in a particular position or operation in a particular area of activity or by detention or up to one year imprisonment."*

Furthermore Article 134 Section 2 of the Criminal Code provides regulation on the prohibition of discrimination based on genetic risk. The referred Article declares that *"unlawful restriction of the rights of a person or conferral of unlawful preferences on a person based on the genetic risks of the person is punishable by a fine, detention or up to one year imprisonment."*

The aforementioned provisions of the Criminal Code are of great importance and all of them were entered into force by the adoption of the Human Genes Research Act in 2001.

It is also worthwhile to mention that the prohibition of discrimination on the basis of genetic risk in the Criminal Code is in line with Articles 25-27 of the HGRA. Article 25 of the Human Genes Research Act provides a general prohibition clause on discrimination by means of stating that it is prohibited to restrict the rights and opportunities of a person or to confer advantages on a person on the basis of the structure of the person's DNA and the genetic risks resulting therefrom. Article 26 of the Human Genes Research Act sets out provisions on the prohibition of dis-

crimination in employment relationship and Article 27 sets forth that insurers are prohibited from collecting genetic data on insured persons or persons applying for insurance cover and from requiring insured persons or persons applying for insurance cover to provide tissue samples or descriptions of DNA. Additionally, insurers are also prohibited from establishing different insurance conditions for people with different genetic risks and from establishing preferential tariff rates and determining insured events restrictively.

As it is mentioned before, since 2007 the Estonian Human Genome Project has been incorporated as an independent department into the University of Tartu, thus the EGP falls under the scope of University Act.³²

4. ESTABLISHMENT AND MANAGEMENT OF BIOBANKS

The Human Genes Research Act constituted the legal basis for coordinating the establishment and ownership of the gene bank, and for gathering, processing and disseminating the information related to it and the HGRA also serves as the legal basis for the Estonian Genome Project.

As it is mentioned above Gene Bank means a database established and maintained by the chief processor and in line with the Human Genes Research Act. The duties of chief processor in the Estonian Genome Project are car-

ried out via the Estonian Genome Project Foundation.³³ According to Article 3 of the Human Genes Research Act, the Estonian Genome Project Foundation “has the right to organize the taking of tissue samples, to prepare descriptions of state of health and genealogies, to code, decode, store, destroy and issue descriptions of state of health and genealogies, to perform genetic research and to collect, store, destroy and issue genetic data”.

Section (2) of Article 3 also sets forth that the objectives of the chief processor are to (1) promote the development of genetic research; (2) collect information on the health of the Estonian population and genetic information concerning the Estonian population; (3) use the results of genetic research to improve public health.

Section (3) of the same article also provides that *“In order to achieve its objectives, the competence of the chief processor includes the establishment and maintenance of the Gene Bank. The chief processor has the right to delegate the rights of processing, except for coding and decoding, to an authorised processor on the basis of a contract in the cases and under the conditions prescribed in this Act.”*

5. PECUNIARY ASPECTS

As it is presented above the financial background of the Estonian Genome Project was uncertain from 2004 to

³² University of Tartu Act, Passed 16 February 1995 (RT I 1995, 23, 333), entered into force 21 March 1995, last amendments are made to the Act on 28.06.2004 entered into force 01.09.2004 - RT I 2004, 56, 404; In original language: Tartu Ülikooli seadus. Official English translation is available at: <http://www.legaltext.ee/en/andmebaas/ava.asp?m=022>

³³ See also the Definition of biobanks

2007, furthermore the whole project was put on halt during this period due to the withdrawal of the private financial funding from the project. Nevertheless the amendment of the Human Genes Research Act in 2007 enables the Estonian Genome Project to continue its operation as a structural unit of the University of Tartu and receive a guaranteed public funding from the Estonian Government.

Participation in the EGP is voluntary and gene donors do not receive any direct financial benefits. According to Article 9 Section (2) of the Human Genes Research Act, in line with Article 124 Section (4) of the Criminal Code, it is prohibited to influence a person's decision to become a gene donor, including by threatening the person with negative consequences, promising material benefits or providing subjective information. Article 12 Section (4) of the HGRA also sets forth that the gene donor is not entitled to request a fee for providing a tissue sample, preparation and study of a description of his or her state of health or genealogy, or use of the research results.

According to Section (1) of Article 14, the chief processor shall organise the taking of tissue samples and the preparation of descriptions of state of health itself or through an authorised processor. Furthermore Section (2) also sets out that the medical procedure of tak-

ing a tissue sample shall be performed by a health care professional (general practitioner or GP) of the Republic of Estonia. Although gene donors are participating in the EGP on a voluntary basis and no financial incentives are provided to them, the general practitioners (GPs), who collect the data and take blood samples from the donors, received incentives for participating in the project and all GPs receive EUR 32-34 per donor.³⁴

6. CONSENT

According to Sections (1)-(2) of Article 8 of General Part of the Civil Code Act³⁵ an active legal capacity of a natural person is the capacity to enter independently into valid transactions. The Civil Code also sets out that persons who have attained their 18 years of age (adults) have full active legal capacity. Nevertheless, in the context of the consent of gene donor considering the taking of samples for the interest of the Estonian Genome Project, Article 13 Section (2) of the HGRA sets forth that persons who are unable to understand the content and meaning of consent shall not be gene donors. In the case of doubt, it is presumed that the person is temporarily unable to understand the content and meaning of consent.

Article 11 of the Personal Data Pro-

³⁴ Ensaar, Rain: Estonia, Ups and Downs of Biobank Project In: Herbert Gottweis and Alan Petersen (eds.), *Biobanks: Governance in Comparative Perspective*. Routledge, 2008, Part 4.

³⁵ General Part of the Civil Code Act. Passed 27 March 2002 (RT I I 2002, 35, 216), entered into force 1 July 2002, amended by the following Acts: 19.11.2003 entered into force 27.12.2003 - RT I 2003, 78, 523; 15.01.2003 entered into force 01.07.2003 - RT I 2003, 13, 64. In original language: Tsiviilseadustiku üldosa seadus. Official English translation is available at: <http://www.legaltext.ee/en/andmebaas/tekst.asp?loc=text&dok=X30082K2&keel=en&pg=1&ptyyp=RT&tyyp=X&query=Civil+Code>

tection Act sets forth that personal data may be processed only with the permission of the data subject, unless otherwise provided by law. In addition to the above Article 12 defines the consent of the data subject for the processing of personal data and states that it means a freely given specific and informed indication of the wishes of a data subject by which the data subject signifies his or her agreement to personal data relating to him or her being processed. Article 12 Section (2) sets out the obligation of the chief processor to notify the data subject prior to obtaining his or her consent on (1) the purpose of processing of the personal data; (2) persons or categories thereof to whom transmission of the personal data is permitted; (3) the name of the chief processor or a representative thereof and the address of the place of business of the chief processor; (4) the cases when the data subject has the right to demand termination of processing of the personal data and rectification, blocking or erasure of the personal data; (5) the cases when the data subject has the right to obtain access to the personal data pertaining to him or her.

Section (3) of Article 12 sets forth regulation on the validation of the given consent and provides that the consent of a data subject shall be valid during the life of the data subject and thirty years after the death of the data subject, unless the data subject has decided otherwise.

It also has to be noted, that in the case of a dispute, a data subject is pre-

sumed not to have granted consent for the processing of personal data relating to him or her.

Nevertheless it is also important to set out that the Human Genes Research Act provides special legislative background considering the operation of the biobank and data protection of the gene donors involved in the EGP.

Both the Human Genes Research Act and the entire Estonian Genome Project are based on the principle of expressed informed consent. In order to become a gene donor, a person has to go through a counselling process and then sign a written gene donor consent form. Although the written information on the Project is easily available for the gene donors, the written information cannot substitute personal discussions between the gene donor and his or her GP. Therefore, the procedure of obtaining consent from a gene donor constantly underlines the need of discussing the issues concerning the donation with the possible gene donor. In line with Article 12 Section (7) of the Human Genes Research Act, format of written consent to become a gene donor and the procedure for the completion and preservation thereof is established by Decree No. 125 of the Minister of Social Affairs.³⁶ According to Article 12 Sections (1)-(2), a person's consent to provide a tissue sample, to have a description of the state of health or the genealogy of the person prepared, to enter the description of the state of health or the genealogy in the Gene Bank in coded form and to use thereof for genetic re-

³⁶ Format of gene donor's consent and the procedure for the completion and preservation thereof, Decree No. 125 of the Minister of Social Affairs. See also footnote 25. The Gene Donor Consent Form of the EGP is available at: <http://www.geenivaramu.ee/index.php?id=104>

search, public health research and statistical purposes shall be prepared in writing and shall be signed by the person who becomes a gene donor. It also has to be noted that partial or conditional consent is not valid.

The written consent form covers the following main aspects, as also stated in Article 12 Section (4) of the HGRA: the (1) granting of the consent is voluntary; (2) the gene donor is not entitled to request a fee for providing a tissue sample, preparation and study of a description of his or her state of health or genealogy, or use of the research results; (3) data on hereditary characteristics and genetic risks obtained as a result of genetic research may be unpleasant for the gene donor; (4) the gene donor has the right not to know his or her genetic data; (5) the gene donor has the right to know his or her genetic data, except genealogy; (6) the gene donor has the right to apply to the chief processor for the destruction of data which enables decoding or, upon unlawful disclosure of his or her identity, for the destruction of the tissue sample, description of DNA, and description of his or her state of health; (7) the gene donor has the right to withdraw his or her consent until his or her tissue sample or his or her health data are coded. Moreover, additionally to information which was received by the gene donor on his or her rights and on the possible consequences of donating tissue samples and health descriptions, many other important details should also be disclosed to the donor, such as the de-

scription of the operation of the EGP, the aims and financial background of the project, the possible further uses of data, ownership of data and samples, and coding and decoding procedures. Additional information is available in the form of the so-called 'gene donor information kit' which contains leaflets, contact information, the text of the HGRA, etc. Even though Russian is not an official state language of Estonia, all the documents are translated into Russian.³⁷

Concerning the withdrawal of the gene donor's consent Article 12 Section (4) point 7) sets forth that gene donors have the right to withdraw their consent until tissue samples or the descriptions of state of health are coded and in such case, the gathered information and blood sample shall be terminated. Afterwards, a gene donor has the right to apply, at any time, to the chief processor for the destruction of data that enables decoding within two weeks from the receipt of the corresponding written application from the gene donor (Article 20 Section (1)). However, destruction of data that enables decoding (i.e. anonymization) does not mean also the destruction of biological material or other data.³⁸ In line with Article 10 Section (2) of the HGRA, a gene donor has the right to request termination of biological material and other data available in the Gene Bank if the identity of a gene donor is unlawfully disclosed. After the data that allows decoding is destroyed, the health data and the tissue samples of a gene donor, stored in the Genome Bank, are anonymous. Thus, the regu-

³⁷ Nõmper and Kruuv 2003

³⁸ Nõmper and Kruuv 2003

lation of personal data protection does not apply, since it does not extend to data processing performed with anonymized data in line with Article 7 Section 2.

6.1. CONSENT OF PEOPLE LIMITED LEGAL CAPACITY AND DECEASED PERSONS

Provision on persons having restricted legal capacity are set out in Article 8 Sections (2)-(3) of the General Part of the Civil Code Act according to which persons who are under 18 years of age (minors) and persons who due to mental illness, mental disability or other mental disorder are permanently unable to understand or direct their actions, have restricted active legal capacity. Furthermore Section (3) provides that if a guardian is appointed by a court to a person who due to mental illness, mental disability or other mental disorder is permanently unable to understand or direct his or her actions, the person is presumed to have restricted active legal capacity.

Article 13 Section (1) of the Human Genes Research Act sets forth that the consent of a person with restricted active legal capacity to participate in the ECP and become a gene donor shall be deemed valid if (1) the person with restricted active legal capacity and his or her legal representative or guardian have been given the information provided for in Subsection 12 (4) of the Act; and (2) the legal representative or guardian has expressed the consent provided for in Subsection 12 (1) of the Act; and (3) the person with restricted active legal capacity is not opposed to providing a tissue sample or to the col-

lection of descriptions of his or her state of health.

Considering the processing of personal data after the death of the data subject, the Personal Data Protection Act provides in Article 13 that processing of personal data relating to the data subject is permitted only with the written consent of the spouse, a parent, grandparent, child, grandchild, brother or sister of the data subject, except if consent is not required for processing of the personal data or if thirty years have passed from the death of the data subject.

7. DATA PROTECTION

Article 4 of the Personal Data Protection Act defines personal data as any piece of information relating to an identified natural person or a natural person identifiable by reference to the person's physical, mental, physiological, economic, cultural or social characteristics, relations and associations. While Article 4 Section (2) lists the types of private personal data, Section (3) enumerates the types of sensitive personal data. According to the latter provision, the following shall be deemed sensitive data: data revealing political opinions or religious or philosophical beliefs, except data relating to being a member of a legal person in private law registered pursuant to the procedure provided by law; data revealing ethnic or racial origin; data relating to the state of health or disability; data relating to genetic information; data relating to sexual life; data concerning membership in trade unions; information collected in criminal proceedings or in other proceedings to ascertain an

offence before a public court session or before a judgement is made in a matter concerning an offence, or if this is necessary in order to protect public morality or the family and private life of persons, or where the interests of a minor, a victim, a witness or justice so require.

Chapter 4 of the HGRA deals with data protection issues and Article 22 of the Act provides, that all data in the Gene Bank shall be processed in compliance with the highest standard of data protection. No data shall be issued from the Gene Bank in uncoded form (Article 22 Section (4)), except in cases expressly set forth by the HGRA.³⁹ Article 23 Section (1) sets out that the chief processor shall give each tissue sample, description of DNA, description of state of health and genealogy a unique code consisting of at least sixteen random characters immediately after receipt of the tissue sample, description of DNA, description of state of health or genealogy in the Gene Bank.

Article 7 of the Human Genes Research Act sets out that the provisions of the Personal Data Protection Act together with the specifications provided for in the HGRA, apply to the taking of tissue samples, preparation of descriptions of state of health, coding, decoding, and the maintenance of databases by the chief processor. Section (2) of Article 7 also provides that the processing of coded tissue samples, coded descriptions of DNA and coded

descriptions of state of health are excluded from the scope of the Act, provided that such tissue samples, descriptions of DNA and descriptions of state of health are processed as a set of data and on the condition that the set of data to be processed contains DNA samples, descriptions of DNA or descriptions of state of health of at least five gene donors at a time. The latter provisions of Section (2) provides protection to the gene donor against indirect identification, thus the chief processor may not issue data from the Gene Bank even in coded form if less than five persons can be the source of that information, that is, who meet the criteria of the issued data.

Additionally to the general provisions of the Data Protection Act that sets forth the rights of an individual in relation to his or her privacy, in the context of biobanks, the Human Genes Research Act provides the gene donors with the following rights: (1) confidentiality of identity of gene donors; (2) the voluntary nature of gene donation; (3) right to apply for destruction of material; (4) the right not to know their genetic data; (5) the right to access personally their data stored in the Gene Bank; (6) the right to access their data stored in the Gene Bank for free; (7) the right to genetic counselling upon accessing their data stored in the Gene Bank; (8) the right to submit additional information on themselves to the chief processor; (9) the right to prohibit the supplementation, renewal and verification of

³⁹ The Human Genes Research Act specify two explicit exemption and allow the data processing of uncoded data in the following cases: (1) the doctor of a gene donor has the right, [...] to obtain the decoded description of the state of health of the gene donor from the Gene Bank in order to treat the gene donor (Article 16, Section (2)). (2) Gene donors have the right to access personally their data stored in the Gene Bank, however they do not have the right to access their genealogies [Article 11, Section (2)].

descriptions of their state of health stored in the Gene Bank. Nevertheless, the gene donors do not have the right to access their genealogies.

It is worthwhile to emphasize that according to Article 33 of the Personal Data Protection Act if the rights of a data subject are violated in the processing of personal data the aggrieved person is entitled to claim compensation for the damage caused to the data subject on the basis and pursuant to procedure provided for in the State Liability Act⁴⁰ if the rights are violated in the course of performance of public duties or on the basis and pursuant to procedure provided for in the Law of Obligations Act⁴¹ if the rights are violated in a private law relationship.

As it is mentioned above the medical procedure of taking a tissue sample is performed by a health care professional who also collects health data of the gene donor and submits the data and blood sample to the EGP in a secured form, keeping the identity of the gene donor confidential. In the interests of greater security EGP may carry out further coding of information according to which the chief processor may give an additional code to a coded sample and this code shall replace the initial code given to the sample. The chief processor shall make a record of the link between an initial code and an additional code in a database used solely for

that purpose and is entitled to process the data [Article 23 Section (4)].

Article 24 of the Data Protection Act provides the relevant regulation in relation to the administrative obligation imposed on the chief processors to register processing of sensitive personal data with the Data Protection Inspectorate. A chief processor who applies for an activity licence or a licence in an area of activity which involves processing of sensitive personal data is, before application for the activity licence or licence, required to register the processing with the Data Protection Inspectorate. The activity licence or licence shall not be issued unless the processing of personal data is registered. Processing of sensitive personal data shall be registered for a term of five years. At least three months before expiry of the term, a chief processor is required to submit a new registration application which complies with the requirements of Article 25 of the Personal Data Protection Act. Upon expiry of the term, the chief processor loses the right to process sensitive personal data.

8. STORAGE

According to the relevant provisions of the Human Genes Tissue Act the chief processor is obliged to code the ob-

⁴⁰ State Liability Act Passed 2 May 2001, (RT I 2001, 47, 260), entered into force 1 January 2002, 2002, 62, 377 In original language: Riigivastutuse seadus. Official translation is available at: <http://www.legaltext.ee/en/andmebaas/tekst.asp?loc=text&dok=X40075K2&pg=1&tyyp=X&query=State+Liability+Act&ptyyp=RT&keel=en>

⁴¹ Law of Obligations Act (05.06.2002 entered into force 01.07.2002 - RT I 2002, 53, 336) Passed 26 September 2001 (RT I 2001, 81, 487), entered into force 1 July 2002. In original language: Võlaõigusseadus. Official translation is available at: <http://www.legaltext.ee/en/andmebaas/tekst.asp?loc=text&dok=X30085K2&pg=1&tyyp=X&query=Law+of+Obligations+Act&ptyyp=RT&keel=en>

tained samples and as a result the sixteen digit code replaces any information that could enable identification (Article 23 Section (2)). In line with Article 23 Section (3) of the HGRA, the same code will be noted on the consent form, therefore the consent form of the gene donor will be the only possible way for decoding.

The data processing is strictly supervised by the Data Protection Inspectorate thus the chief processor shall obtain the approval of the data protection supervision authority for the method of generating the codes as set out in Article 23 Section (1).

Occurrence of data leakage is potentially most harmful to the gene donors, since it allows decoding their tissue sample or description of DNA and so on and therefore breaches their confidentiality and their rights to privacy. The HGRA set up several defending methods to avoid the disclosure of personal data of the gene donor. First of all, data enabling identification of gene donors shall not be available through the external computer network of the Gene Bank (Article 22 Section (2)). Article 22 Section (3) also provides that only a few members of the EGP staff shall have access to such data. The chief processor shall appoint the specific persons who perform coding or decoding, who have access to the consent of gene donors, to the collection of tissue samples and descriptions of DNA, to descriptions of state of health and to genealogies, and who issue coded or uncoded tissue samples, descriptions of DNA or descriptions of state of health. Article 24 of the HGRA

sets out the cases when the Human Genes Research Act permits decoding.

Article 18 Section (1) of the Human Genes Research Act provides that the tissue samples, descriptions of DNA and descriptions of state of health shall be stored by the chief processor or an authorised processor, however the coded samples may also be stored by a gene researcher who has the resources and conditions necessary for storage. The conditions for storage shall be established by the Minister of Social Affairs by Decree No. 127 on the conditions for storage of DNA samples, coded descriptions of DNA and coded descriptions of state health.⁴² In order to organise storage, the chief processor shall enter into a contract with an authorised processor or gene researcher which shall set out (1) the tissue samples, descriptions of DNA and descriptions of state of health handed over for preservation; (2) the time of delivery of the tissue samples, descriptions of DNA and descriptions of state of health to the authorised processor or gene researcher and the manner of supplementing the tissue samples, descriptions of DNA and descriptions of state of health; (3) the place and term of storage; the method of storage; (4) the security measures to be applied by the storer; (5) the procedure for the copying, distribution, destruction and issuing of tissue samples, descriptions of DNA or descriptions of state of health and for the return thereof to the chief processor or authorised processor; (6) the liability of the authorised processor or gene researcher.

All tissue samples shall be stored on the territory of the Republic of Estonia.

⁴² See also footnote 28.

The Government of the Republic may, at the request of the chief processor and if good reasons therefore become evident, grant permission for tissue samples to be stored outside the territory of the Republic of Estonia if it is ensured that the chief processor has effective control over the tissue samples and that the tissue samples cannot be used in a manner prohibited by Estonian law.

It also has to be noted that for the protection of personal privacy of the gene donors Article 24 Section (2) of the HGRA provides that only persons appointed pursuant to Article 22 Section (3) of the Act may gain access to the written consent with a code indicated thereon and have the technical possibility to decode data.

Furthermore Article 24 Section (2) sets forth that the chief processor is permitted to decode data only in the cases and for the purposes as set out in the Human Genome Research Act.

9. SUPERVISION, COMPENSATION, PENALTIES

As it is mentioned before, according to the Human Genes Research Act, the responsible Ministry is still the Ministry of Social Affairs who is in charge of the supervision over the Estonian Genome Project. Additionally, after 2007 the scope of the University Act is also applicable to the EGP therefore a certain supervising power over the Project is given to the Ministry of Education and Research and to the National Audit Office of Estonia in line with Articles 52 and 53 of the University Act.

Article 4 of the Human Genes Research Act provides provisions on the supervisory board of the Gene Bank's chief processor. Section (1) of Article 4 sets out that the supervisory board of the chief processor of the Gene Bank shall consist of nine members. The Estonian Parliament shall, on the proposal of its Social Affairs Committee, appoint three members of the supervisory board and additionally the Government of the Republic shall appoint three further members while the Board of the Estonian Academy of Sciences shall appoint another three members of the supervisory board. The term of authority of a member of the supervisory board is from one year to five years. The due date for termination of the authority of a member of the supervisory board shall be determined upon appointment of the member of the supervisory board. If a member of the Parliament or the Government of the Republic is appointed to the supervisory board, this member's authority shall terminate with the end of his or her membership in the appointed body.

The body which appointed a member of the supervisory board may remove the member of the supervisory board with good reason, which is, above all, failure to perform his or her duties to a material extent, a constant conflict of interests or inability to participate in the work of the supervisory board or the causing of significant damage to the interests of the chief processor of the Gene Bank in any other manner, and also the commencement of bankruptcy proceedings against the member of the supervisory board.

The Data Protection Inspectorate⁴³ is a supervisory authority for the surveil-

⁴³ <http://www.aki.ee/eng/>

lance of the Personal Data Protection Act and the Databases Act, thus it has supervising power over the EGP as well. The Inspectorate, is operated as a division of the Ministry of Internal Affairs. It monitors compliance, issues licenses, takes complaints, and settles disputes. In the interest of performing its duties the Inspectorate is entitled to conduct investigations and demand documents, impose fines, and impose administrative sanctions. As it is mentioned above Article 25 of the Personal Data Protection Act sets forth that chief processors are obliged to register processing of sensitive personal data with the Data Protection Inspectorate. Article 27 also provides that the Data Protection Inspectorate is obliged to maintain a register of processors of personal data pursuant to the procedure established by the Government of the Republic in which notices concerning the processing of private personal data and information concerning registration of processing of sensitive personal data are registered. Although the data entered in the register are informative, the entries concerning the registration of processing of sensitive personal data have legal effect.

Although the Human Genes Research Act explicitly excluded gene testing from its scope, it is worth to mention the general provisions on the supervision of clinical trials in Estonia. According to the Medicinal Products Act approval by an ethics committee is mandatory for clinical trials. The State Agency of Medicines⁴⁴ is the extra-judicial body which conducts proceedings

in the case of misdemeanours in clinical trials and is entitled to suspend clinical trials and impose fines. Relevant laws applicable are the Medicinal Products Act and the Code of Misdemeanour Procedure.

There are independent ethics committees that consider medical research and clinical trials in Estonia, the Human Research Ethics Committee at the University of Tartu⁴⁵ and the Medical Research Ethics Committee operated next to the National Institute for Health Development, Tallinn. The ethics committees of hospitals are not responsible for clinical trials and medical research. In addition to the above mentioned ethics committees, the Estonian Council of Bioethics is also worth mentioning as the national co-ordinating centre in bioethical issues. It is an advisory body to health authorities and government and provides policy advice across a wide range of "bioethics" topics, as well as determines the ethical standards or policies for research involving human beings and reviews research projects. The Estonian Council of Bioethics is established by the Ministry of Social Affairs which is also responsible for determining the requirements for membership, and the remit of, ethics committees.

In relation to the respective legal domain, the ethical supervision of biobanks in Estonia is conducted by a separate ethics committee that deals solely with the Estonian Genome Project. The aim of the Ethics Committee is to provide assistance in ensuring the protection of the health, human

⁴⁴ <http://www.ravimiamet.ee/215>

⁴⁵ Further information is available at the website of the Centre for Ethics of Tartu University at: <http://www.etikakeskus.ut.ee/> and at the website Ethics in Science in Estonia at: <http://www.ethics.ut.ee/>

dignity, identity, security of persons, privacy and other fundamental rights and freedoms of gene donors and resolution of general ethical problems related to human gene research. Both the functions and rights of the Ethics Committee of EGPF are covered by the Human Genes Research Act. The members of the Bioethics Committee are appointed by the Supervisory Board of the EGPF and may be removed by them also. The task of the Ethics Committee is to draw the attention of the Supervisory and Management Boards of the Genome Project to circumstances that might be in conflict with ethical norms. Pursuant to its statutes, the Committee presents an annual report on the activities and most important opinions of the Ethics Committee to the Supervisory Board and the Management Board of the Genome Project. Everybody can address the Ethics Committee of the Genome Project to receive information, advice or an assessment of the Committee about matters related to the Project. Assessments and resolutions of the Ethics Committee are independent and impartial. To ensure independence, the costs of the operations of the Ethics Committee are covered with funds allocated from the state budget.

Article 29 of the HGRA sets out the general provisions in relation to the separate ethics committee for the Estonian Genome Project, that is established in order to facilitate the ethical assessment of activities conducted in the framework of the Estonian Genome Project. According to the HGRA the assessment of the Ethics Com-

mittee is not binding, except in case the identification of the gene donor is needed on the proposal of the chief processor in order to contact the gene donor and to renew, supplement or verify a description of his or her state of health with his or her written consent (Article 24 Section (2) point 4). In the latter case the assessment of the Ethics Committee is indispensable and the assessment thereof is binding to the parties.

Considering the composition of the Ethics Committee, Article 29 Section (3) declares that each member of the Ethics Committee shall be an Estonian citizen with active legal capacity whose permanent residence is in the Republic of Estonia. Each member of the Ethics Committee shall be a recognised specialist in his or her field with the necessary expertise to perform the duties of a member of the Ethics Committee and shall have an impeccable reputation. The members of the Ethics Committee shall be appointed for a five year term and the number of members shall be determined by the supervisory board of the chief processor of the Gene Bank.

The supervisory board of the chief processor of the Gene Bank may remove a member of the Ethics Committee prior to expiry of the term of authority of the member with good reason, which is, above all, failure to perform his or her duties to a material extent, inability to participate in the work of the Ethics Committee or the causing of significant damage to the interests of the chief processor in any other manner, and also the commencement of bankruptcy proceedings against the member of the Ethics Committee.

II. FORENSIC BIOBANKS

1. DEFINITION OF FORENSIC BIOBANKS

Although the definition of forensic database is not specified in the Estonian legislation, Article 13 Section (3) of the Police Act sets out that the Government of the Republic is entitled to establish the national DNA register for processing of the data obtained as a result of DNA probes taken by the police on the basis of Police Act and the data obtained as a result of DNA probes taken by other agencies pursuant to law and forwarded to the police. The Government of the Republic Regulation No. 259 of 14 December 2006 regarding the establishment of a National DNA Register and Statutes for the Maintenance of the Register⁴⁶ also states that the database consists of data, which have been col-

lected by the police in accordance with the law as a result of a DNA sample analysis, or which has been collected by other authorities in accordance with the law as a result of a DNA sample analysis. (Article 3)

2. RELEVANT LAWS

The legal background of the National DNA Database is based on Government of the Republic Act, Databases Act,⁴⁷ Police Act,⁴⁸ Personal Data Protection Act,⁴⁹ Code of Criminal Procedure⁵⁰ and Government of the Republic Regulation No. 259 of 14 December 2006 regarding the establishment of a National DNA Register and Statutes for the Maintenance of the Register and Decree of the National

⁴⁶ Government of the Republic Regulation No. 259 of 14 December 2006 regarding the establishment of a National DNA Register and Statutes for the Maintenance of the Register. Adopted with the Resolution no 259 of the Government of the Republic (RT I 2006, 57, 434) dated 14. December 2006, entry into force 24. December 2006.

⁴⁷ See footnote 31.

⁴⁸ Police Act (21.04.93 entered into force 06.05.93 - RT I 1993, 20, 355) Passed on 20 September 1990 (RT I 1990, 10, 113), entered into force 1 March 1991. In original language: Politseiseadus. Official English translation is available at:

<http://www.legaltext.ee/en/andmebaas/tekst.asp?loc=text&dok=X60006K5&pg=1&tyyp=X&query=Police+Act&ptyyp=RT&keel=en>

⁴⁹ See footnote 30.

⁵⁰ Code of Criminal Procedure Passed 12 February 2003 (RT I 2003, 27, 166; consolidated text RT I 2004, 65, 456), entered into force 1 July 2004. In original language: Kriminaalmenetluse seadustik. Official English translation is available at:

<http://www.legaltext.ee/en/andmebaas/tekst.asp?loc=text&dok=X60027K5&pg=1&tyyp=X&query=Code+of+Criminal+Procedure&ptyyp=RT&keel=en>

Police Commissioner No. 51 of 10 February 2004.⁵¹

Among the rights of the police, Article 13 Section (3) of Police Act sets forth that *“the Government of the Republic shall establish the national DNA register for processing of the data obtained as a result of DNA probes taken by the police on the basis of clause (1) 9 (2) of this section and the data obtained as a result of DNA probes taken by other agencies pursuant to law and forwarded to the police and shall establish the statutes thereof.”*

Article 13 Section (1) Point 9 (2) of the Police Act entitled the police to take DNA probes from persons specified Point 9 (1). The enlisted persons who may be subjected to DNA probes are as follows:

“persons suspected of commission of criminal offences, the accused, convicted offenders, persons punished by detention, persons with regard to whom probation has been applied, persons who are released on parole, asylum seekers, aliens staying in Estonia illegally and aliens in respect of whom prohibition on entry is applied.”

According to Article 63 of the Criminal Procedure Act *“Evidence’ means the statements of a suspect, accused or victim, the testimony of a witness, an expert’s opinion, the statements given by an expert upon provision of explanations concerning the expert’s report, physical evidence, the reports on investigative activities, minutes of court sessions and the reports on surveillance activities, and any other documents, photographs, films or other data recordings.”*

In addition to the above, further evidence may also be used in order to prove the facts relating to a criminal proceeding.

Article 64 of the Criminal Procedure Code provides the general conditions for collection of evidence, according to which evidence shall be collected in a manner which is not prejudicial to the honour and dignity of the persons participating in the collection of the evidence, does not endanger their life or health or cause unjustified proprietary damage. Evidence shall not be collected by torturing a person or using violence against him or her in any other manner, or by means affecting a person’s memory capacity or degrading his or her human dignity.

If it is necessary to undress a person in the course of a search, physical examination or taking of comparative material, the official of the investigative body, the prosecutor and the participants in the procedural act, except health care professionals and forensic pathologists, shall be of the same sex as the person. It is worthwhile to mention that if technical equipment is used in the course of collection of evidence, the participants in the procedural act shall be notified thereof in advance and the objective of using the technical equipment shall be explained to them.

Additionally the Public Information Act is also important in relation to forensic biobanks. According to Article 39 of the Public Information Act in order to ascertain the truth in criminal proceedings and ensure the security of persons, a competent official conducting an investigation or state supervi-

⁵¹ Further information is available on the organizational structure and operation of the Estonian Police at: <http://www.politsei.ee/>

sion may grant access to information classified as internal which contains personal data. If compliance with a restriction on access may endanger the life, health or property of other persons, the restricted information shall be promptly disclosed.

3. ESTABLISHMENT OF FORENSIC DATABASE

Article 13 Section (3) of the Police Act and the Statute of Foundation and Maintenance of the National DNA Database which entered into force by Resolution No. 259 of the Government of the Republic at the end of 2006 provides the legal basis for the foundation of a National DNA Database.⁵² Article 3 of the Resolution provides that the purpose of foundation and maintenance of the database shall be processing of data, which has been collected by the police in accordance with the law as a result of a DNA sample analysis, or which has been collected by other authorities in accordance with the law as a result of a DNA sample analysis and forwarded to the database.

4. MANAGEMENT OF FORENSIC BIOBANKS

According to Article 2 of the Resolution while the chief processor of the database shall be the Ministry of Justice,

the authorised processor of the database shall be the Estonian Forensic Science Institute.⁵³ On the basis of Article 4 of the Resolution, the chief processor is entitled to prepare instructions governing management and operation of the database.

Article 9 sets out that the following entities have access to the Database: (1) investigative bodies (including authorities administered by them and local authorities) specified in Article 31 of the Criminal Procedure Code;⁵⁴ (2) body conducting extra-judicial proceedings; (3) Prosecutor's Office; (4) Court; (5) prisons; (6) Border Guard Administration; (7) Citizenship and Migration Board; (8) state forensic institutions. As a general principle Article 13 of the Resolution sets out that persons processing data are obliged to maintain in secrecy those personal data that have become known to them during the processing of data in the database. According to Article 16 of the Resolution the submitter of data shall be responsible for accuracy of data submitted to the database and if the submitter of data discovers that he or she has submitted inaccurate data to the database, he or she is obliged to immediately submit the corrected data. The authorised processor has the right to make inquiries to the submitter of the data about the correctness of the data and to verify the correctness of the data via other databases.

According to Article 19 of the Reso-

⁵² In original language: *Riiklik DNA register*

⁵³ In original language: Eesti Kohtuekspertiisi Instituut (EKEI) http://www.ekci.ee/?set_lang_id=2

⁵⁴ The following bodies are investigative bodies in the context of the Criminal Procedure Act: the Police Board, Central Criminal Police, Security Police Board, Tax and Customs Board, Border Guard Administration, Competition Board and the Headquarters of the Defence Forces are investigative bodies within the limits of their competence. The aforementioned bodies shall perform the functions of an investigative body directly, through the bodies administered by them or through their regional offices.

lution the foundation and maintenance of the database shall be financed from the state budget as earmarked payments from the budget line of the Estonian Forensic Science Institute. In addition to the above the same Article of the Resolution also sets forth that the Data Protection Inspectorate shall supervise the legality of maintenance of the database. Supervision over maintenance of the database shall be executed by the chief processor of the database.

5. SAMPLES AND SAMPLE TAKING, CONSENT

According to Article 6 of the Resolution the sample's code, reference to the source document and DNA profile shall be entered in the electronic database in case of a depersonalised DNA sample.

In case of a DNA sample taken from a person (personalised DNA sample) however, in addition to the aforementioned list, a person's given name, surname, personal identification code or birth date will be added in the electronic database. If a person has had other names, those will also be added to the database. Article 7 also states that data entered in the database have legal effect to the extent provided by law. Article 10 of the Resolution also sets out that the authorised processor shall enter data in the database at the latest within five working days after acquiring of the DNA profile.

The police have the authority to coercively take a DNA sample from crime

suspects and convicted offenders and there are no restrictions to the collection of crime scene stains. The police are allowed to take a DNA sample from minors.

6. PURPOSE AND SCOPE OF COLLECTION

The DNA profiles of crime suspects and convicted offenders can be entered into the database when they are suspected or convicted of any recordable offence. There are no restrictions to the entry of DNA profiles which are derived from unidentified crime scene stains.⁵⁵

7. ACCESS TO DATA AND SAMPLES

The Administrator of the National DNA Database, appointed by the Police Director of the Forensic Service Centre is entitled to provide access data comprised in the database. Scientists and laboratory personnel have access to all data of the DNA samples, DNA profiles and the matches which are established. There are no restrictions attached to the type of offence justifying the searching of the database and for searching in the database the legal order of a magistrate is not necessary. According to a 2006 survey, annually more than 3500 DNA new profiles are searched against database. According to Article 12 of the Resolution data about matching or mismatching of two or more DNA profiles, which indicates respectively of the DNA samples' origin

⁵⁵ Information is based on N. van Camp, et al., National Forensic DNA Databases in the EU, European Ethical-Legal Papers N°9, Leuven, 2007. pp. 44-45.

from the same or different source, shall be released from the database to the manager of the authority or person conducting proceedings in the authority, which submitted the DNA profile or the application. In case of a matching report the name of person(s), the number of the criminal matter and details of the sample are being provided. Upon a request from another Member States to perform a search in the Estonian National DNA Database, the information that is transmitted to the other country are the DNA profile, unique identifier and the name and type of the committed offence. In case of matching profiles between the Estonian Database and another database in another Member State, the transmitted information are the identity of the profile and the type of offence.

Article 5 of the Police Act sets out the general prohibition on the disclosure of the data comprised in the National DNA. According to the referred Article of the Police Act data in the database shall not be disclosed publicly. Article 11 of the Resolution defines the bodies that are entitled to receive data or have access to the database. According to the aforementioned Article of the Resolution, the following bodies are granted with the right to have access to the National DNA Database:

- 1) state forensic institution for performance of duties assigned to it by law or legislation enacted pursuant to a law;
- 2) authority taking DNA analysis for performance of duties assigned to it by law or legislation enacted pursuant to a law;
- 3) investigative bodies for performance of duties assigned to them by law or legislation enacted pursuant to a law;
- 4) surveillance agencies or security authorities for performance of duties assigned to them by law or legislation enacted pursuant to a law;
- 5) body conducting extra-judicial proceedings for performance of duties assigned to them by law or legislation enacted pursuant to a law;
- 6) a person with rights of conducting proceedings in connection with the criminal proceeding underway;
- 7) Court and Prosecutor's Office for performance of duties assigned to them by law;
- 8) Border Guard Administration for performance of duties assigned to it by law;
- 9) Citizenship and Migration Board for performance of duties assigned to it by law;
- 10) foreign official in accordance with international conventions, international agreement or inter-agency cooperation agreement;
- 11) other persons for access to information kept about those persons in the database.

In addition to the above the authorised processor is entitled to release data about existence of DNA profiles to authorities or persons listed in Article 11 upon written inquiry.

Article 14 of the Resolution also sets forth that the chief processor and the authorised processor of the database can submit inquiries and receive data from other national or local databases for performance of duties assigned to them by law or legislation enacted pursuant to a law, in accordance with the agreement between chief processors

of the databases complying with the Resolution of the Government of the Republic No. 78 dated 24 April 2008 on "Data link layer of information system".

According to Article 12, data can be sent to other countries to fulfil an obligation arising from the law of the European Union; or in cases and in the matter prescribed in international conventions, international agreements or inter-agency cooperation agreement.

The international exchange of information is allowed, based on criminal conventions, international agreements or state agency agreements such as the Estonian and Lithuanian⁵⁶ exchange agreement signed on 17 June 2008 and the Estonian and Finnish⁵⁷ forensic data exchange agreement entered into force in 2007. The cooperation in comparing DNA analysis with Finland and Latvia has proved as an effective method of crime detection, which all the countries participating in data exchange have benefited from. Cooperation with Finland, which started at the end of last year, has yielded favourable results. 25 matches were found for the profiles sent from Estonia to Finland in the Finnish DNA register. In case of 13 different crimes committed in Finland evidence was matched to 11 persons in the Estonian DNA register, including one person whose data had been stored in the Estonian register, and who was associated with various crimes in Finland. As a result of DNA profile exchange with Latvia, matches were made between two crime scene traces in Estonia and two

persons whose data had been stored in the Latvian register and there was one match found between a crime scene in Estonia and Latvia. In addition to the above the DNA profile information can be exchanged with other EU Member States through Interpol contact points.

8. STORAGE

The National DNA Database contains data related to biological samples, DNA profiles and DNA matches. The searches that are available on the data involved in the database for matching profiles can be requested by crime scene/crime scene, suspect/crime scene, suspect/suspect, missing person/crime scene, deceased person/suspect.

The Resolution sets out several security measures for the maintenance of the National DNA Database. According to Article 15 the rules on staying on the working premises and receiving of guests shall be prescribed in the internal procedure rules of the authorised processor. Furthermore, processing equipment of the database shall be kept in locked rooms with safety installations, where only authorised persons have access to. The right to enter, record data or make inquiries shall be designated by user groups. The rights of the officials of the authorised processor to use the database shall be designated by job descriptions. Remaining within the limits of the rights shall

⁵⁶ Estonian and Lithuanian forensic scientists begin to exchange DNA data. 17 June 2008 http://www.politsei.ee/?mid=5&mcid=11658&ctype=news_article&pageid=1094

⁵⁷ New Estonian-Finnish project will help solve crimes 11 December 2007

http://www.politsei.ee/?mid=5&mcid=11378&ctype=news_article&pageid=1094

be supervised with measures involving software. Data about who and when has been used, shall be kept as database log files with measures involving software, which shall be kept for two years; after the end of data storage, the saved data shall be deleted immediately.

According to Article 18 personalised data shall be preserved in the database for 10 years after the death of the relevant person, whereupon the relevant data shall be deleted from the electronic database. Depersonalised data shall be preserved in the database for 75 years, whereupon it shall be deleted from the electronic database. If the authorised processor discovers a

match between a personalised DNA sample and a depersonalised DNA sample, the depersonalised sample shall be deleted from the electronic database after notification of the match. The source documents shall be preserved in files on paper and in electronic mediums and the preservation shall be performed in accordance with Archives Act.⁵⁸

The DNA profiles of crime suspects and convicted offenders have to be removed from the forensic DNA database ten years after the passing away of the person concerned. The DNA profiles that are derived from unidentified crime scene stains have to be removed 75 years after their entry.

⁵⁸ Archives Act Passed 25 March 1998 (RT I 1998, 36/37, 552), entered into force on 1 May 1998. In original language: Arhiiviseadus. Official English translation is available at: <http://www.legaltext.ee/en/andmebaas/tekst.asp?loc=text&dok=X2058K5&pg=1&tyyp=X&query=Archive&ptyyp=RT&keel=en>





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