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THE LEGAL REGULATION
OF BIOBANKS

National Report:
Latvia



CENTER FOR ETHICS AND LAW
IN BIOMEDICINE





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Judit Sándor and Petra Bárd

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

In the framework of the European Union Framework Project entitled “GeneBanC: Genetic bio and dataBanking: Confidentiality and protection of data” we are exploring the legal regulations of data-banks. (<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 fits into the series of country reports prepared by CELAB.

In the present booklet the legal regulation of classical and population biobanks in Latvia will be discussed jointly in Part I, whereas forensic biobanks invoking legal issues of different nature will be covered separately in Part II. The present analysis does not cover either the international standards, or the pieces of European Union law, but it should be borne in mind that they are binding on Latvia being a European Union Member State.

Budapest, 1 May, 2009

CLASSICAL AND POPULATION BIOBANKS

1. THE LATVIAN GENOME PROJECT

The most important biobank-related project in the region – beside the National Genome Database in Estonia – is the Latvian Genome Project. The research project “Unified Genome Database of the Latvian Population”¹ has been submitted to the Latvian government and evaluated by the Prime Minister’s order No. 95 of 14 March, 2000. The collaborative research program “Genomic studies of the Latvian population, their application for diagnosis and prevention of human diseases”² has been approved by the Latvian Council of Science and was launched on 1 January, 2001.

The Project was planned to be established in a 10-year-period, with the threefold major aims of first, creating a unified national network of genetic information and data processing, second, collecting representative amount of genetic material for genotyping the Latvian population and third, comparing the genomic data with the clinical information and medical family history. Phase 1 of the Project between 2001-2003 was devoted to creating a Latvian

network of genetic research groups. In the pilot project phenotypes and genotypes of monogenic diseases made available by the databases of Paul Stradins Clinical University Hospital and the Latvian Centre of Oncology were included. In Phase 2 between 2004-2006 a Unified Genome Database was created including the most common multifactorial diseases. The largest Latvian hospitals participated in this phase. In the final part of the project, Phase 3 between 2007-2009 the comprehensive Genome Database of the Latvian Population will be set up.

The direct advantages of the Latvian Genome Project for the individuals are that everyone will be able to consider his or her risks to develop certain diseases resulting from genetic features and will be able to diminish these risks, mainly through specific therapy based on their genetic characteristics.

Genome-related diseases to be included in the Project were chosen by the following criteria: high frequency of the disease in Latvia and clinical severity, known causing molecular genetic factors, possibilities of treatment and disease prevention, experience in clini-

¹ In original language: Latvijas iedzīvotāju genoma datu bāze.

² In original language: Latvijas populācijas genofonda pētījumi un to izmantošana cilvēka patoloģijas diagnostikā un profilaksē.

cal diagnostics and presence of molecular genetic depositions in Latvia, and finally positive experience in other countries. Monogenic diseases, such as cystic fibrosis, hemophilia B or fragile X syndrome and multifactorial diseases, such as breast cancer, coronary heart disease or obesity have been included. Furthermore the research also aims at studying the Latvian people's ethnogenesis.³

2. DEFINITION OF BIOBANKS

According to Article 1 Points (8)-(9) of the Human Genome Research Act a so-called genome database is a set of data including coded DNA descriptions, coded health status descriptions, coded genealogical and genetic data, coded DNA samples, and coded tissue samples to be used in genetic research, while a gene donor database is a genome database consisting of data that allow the identification of a gene donor and the gene donor's genealogy.

3. RELEVANT LAWS

Apart of laws passed by the Seima, the Parliament of Latvia, regulations and orders of ministries, and ethics committees, such as the Central Medical Ethics Committee of Latvia or the Ethics Committee of the Medical

Academy of Latvia also play an important role in determining the scope of permissible biomedical research and storage of data.

The legal basis of the Latvian genetic research project was established by the Human Genome Research Act,⁴ accepted by the Saeima on 13 June, 2002 and announced by the President on 3 July, 2002, amended by the Saeima on 12 June, 2003 and on 24 February 2005. The original version entering into force on 1 January, 2004.⁵ The law has three main aims: first, to regulate the creation and functioning of the Genome Database of the Latvian Population and related genetic research; second to ensure the voluntary nature of gene donation and the confidentiality of gene donors' identities; and third to protect gene donors from genetic discrimination and misuse of data (Article 2).

The Personal Data Protection Act addresses a number of issues that are relevant in the context of biobanks. The Saeima has adopted the Act – which also implements Directive 95/46/EC into national legislation – on 23 March, 2000 and there has been a major amendment to it on 24 October 2002.

The Reproductive and Sexual Health Act of 2002 lays down the standards and professional obligations in relation to assisted reproduction, storage of

³ For more details see Valdis Pirags and Elmars Grens: The Latvian Genome Project and Aivita Putnina: Population Genome Project in Latvia: Exploring the Articulation of Agency, In: Judit Sándor: Society and Genetic Information: Codes and Laws in the Genetic Era, Budapest – New York: Central European University Press, 2003, 225-246. See also the website <http://bmc.biomed.lu.lv/gene/>.

⁴ In original language: Latvijas populācijas genofonda pētījumi un to izmantošana cilvēka patoloģijas diagnostikā un profilaksē; available at [http://phoebe.vm.gov.lv/misc_db/web.nsf/bf25ab0f47ba5dd785256499006b15a4/17cb8c1218bf81cdc2257313001f391a/\\$FILE/genoms.pdf](http://phoebe.vm.gov.lv/misc_db/web.nsf/bf25ab0f47ba5dd785256499006b15a4/17cb8c1218bf81cdc2257313001f391a/$FILE/genoms.pdf)

⁵ The Human Genome Research Act is reproduced in Judit Sándor: Society and Genetic Information: Codes and Laws in the Genetic Era, Budapest – New York: Central European University Press, 2003, 375-388.

reproductive tissues and the protection of embryos. It has been adopted on 31 January, 2001 and entered into force on 1 July 2002.

The Medical Treatment Act adopted on 5 June, 1997, entering into force on 12 June, 1997, as amended on 1 October, 2007 may also serve as a background legislation.

The protection of human dignity, an the fundamental freedoms and identity of humans with regard to the transplantation is guaranteed by the Act on the Protection of Dead Human Being and Use of Human Organs and Tissues adopted on 15 December 1992, entering into force on 1 January 1993. Amendments of 21 September 1995 and 6 December 2001 modified the text.

Regulation No. 398 of the Cabinet of Ministers on the Storage, Accumulation and Use of Human Organs and Tissues, adopted on 15 July, 2003, entering into force on 19 July, 2003 is more specifically biobank-related.

Regulation No. 312 of the Cabinet of Ministers on Clinical Drugs and Pharmaceutical Products of 12 September 2000 lays down important requirements as to informed consent.

Regulation of the Ministry of Welfare on blood safety No. 260 of 20 September 1995 covers safety requirements on blood, blood components and products derived from blood.

4. ESTABLISHMENT AND MANAGEMENT OF BIOBANKS

In order to start the creation of the Unified Genome Database of the Latvian Population, the Latvian government had to authorize the Main Processor of the Genome Database and establish

the State Population Genome Register after the Human Genome Research Act had come into force on 1 January, 2004. The Genome Research Council is supervising and representing the public interest in genetic research conducted in Latvia.

The Main Processor is a state-owned research institution with international experience. According to Article 4 Section (2) of the Human Genome Research Act the Main Processor is responsible for organizing the obtaining and storage of tissue samples and the preparation, storage, destruction of health descriptions and genealogies. Its other tasks include coding, storage and destroying of tissue samples, health descriptions and genealogies. The Main Processor is also conducting genetic research and has to store results itself. In line with Article 6 the Main Processor has the right to delegate the rights of processing, with the exception of coding and decoding.

The State Population Genome Register is a government organization established in order to create a database of personal data of gene donors, to preserve genetic data and written consents of gene donors received from the Main Processor, and which is supervised by the Ministry of Health. (Human Genome Research Act, Article 7) Its tasks are storage of genetic data obtained in the course of genetic research related to a particular gene donor; establishment of a database of gene donors; and performing decoding.

5. PECUNIARY ASPECTS

The Latvian Genome Project is financed partly by the state through national research and development

programs and projects; international sources, such as the EC PHARE investment program; private investment, e.g. pharmaceutical and biotech companies, banks, insurance companies etc.; and the Latvian Genome Research Foundation. Participation in the Project is voluntary and gene donors do not receive any direct financial benefits.

In other research projects donors have to be informed in writing about compensation in case of injuries resulted from the trial. In clinical trials the sponsors have to conclude insurance policies in order to make sure that possible damages and injuries resulting from the trial are compensated.

6. CONSENT OF PEOPLE WITH FULL AND LIMITED LEGAL CAPACITY, AND DECEASED PERSONS

When conducting clinical studies and also in the Latvian Genome Project gene donors before donation receive written information as to the following issues: aims, purpose, duration and content of the research project, what the study involves (information about obtaining a tissue sample, questionnaire, medical records), data protection, the potential – mainly informational – risks of the project (mainly informational risks), the rights of donors, the possibility of withdrawal of consent without any explanation for such a decision, the right to apply for the destruction of tissue samples or data which enables decoding, and the fact that they will not be remunerated. In clinical studies the objectives, methods, benefits and risks, duration of the research and possible compen-

sation for the donation, furthermore compensation in case of research-related injuries have to be laid down in writing in a language the donor understands.

In the Latvian Genome Project gene donors have the right to submit additional information about themselves to the Main Processor, as well as the right to prohibit the supplementation, renewal and verification of health descriptions stored in the Genome Database. In case of withdrawal, the tissue sample, the description of the DNA, health description and genealogical data all have to be destroyed. In case DNA is taken for clinical studies, it shall be emphasized that withdrawal will not affect future medical care provided for the donor negatively.

In the Latvian Genome Project the consent form has to be signed in two copies by the gene donor and the person appointed by the Main Processor. The consent form has to contain an agreement to provide a tissue sample for the Genome Database, to obtain health description and genealogy, and to use the tissue sample, health description and genealogy for genetic research, public health research and statistical purposes. Each party gets one original copy of the consent form. Consent forms are to be preserved for 75 years after the last change to the agreement is performed. (Article 10 of the Human Genome Research Act)

When it comes to tissue banks, the law on transplantation may offer some guidance. The Act on the Protection of Dead Human Being and Use of Human Organs and Tissues provides that persons may consent to organ donation. Life donations usually involve kidney

transplantation. Organs may be removed and transplanted into another person if this latter patient is on an official waiting list. Once the death of the donor has been determined, certified transplantation may begin, however the doctors participating in the determination and certification of death are not allowed to be involved in the transplantation. There is a presumption for the consent to organ donation in case someone registered for organ donation. Otherwise expressed wishes a person has made during his or her lifetime as to denying or giving consent have to be respected. The transplantation of reproductive organs or tissues, just like embryonic or foetal organs are excluded from the scope of this transplantation law.

Special rules are applicable to a group of persons having legal capacity, i.e. pregnant women, and mothers lactating their children. According to Article 13 of the Regulation No. 312 of the Cabinet of Ministers on Clinical Drugs and Pharmaceutical Products clinical research may not be conducted on these persons, even if they consent to it. Exceptions include cases where the nature of the clinical trial is such that it has to be conducted on pregnant or lactating women and the risks are proportionate to the expected benefits to the embryo, the foetus or the infant.

According to Article 11 of Regulation No. 312 of the Cabinet of Ministers on Clinical Drugs and Pharmaceutical Products whenever a child is to participate in a clinical trial, his or her own desire shall be taken into consideration if the child is about seven years of age. According to Article 12 of the Human Genome Research Act, whenever chil-

dren are involved in the project, their wishes shall be taken into account if they are capable of formulating their views. Research on children's genome is only allowed if a written agreement of the parents or guardian and the orphanage court (parish court) has been obtained. Genome research on adults not having legal capacity should be exceptional, and is only allowed if directly beneficial to the person concerned. In such cases a written agreement of the legal guardian and the Central Medical Ethics Committee is to be acquired.

According to Article 12 of Regulation No. 312 of the Cabinet of Ministers on Clinical Drugs and Pharmaceutical Products unconscious persons or people without legal capacity may only participate in clinical research if the concerned medical product's clinical ethics committee approved of it. Consent shall be given by the closest relatives of the unconscious person in the following order: spouse, parent (or guardian), child. Should the person concerned not have legal capacity, consent is to be acquired from his or her legal representative.

7. DATA PROTECTION

Article 2 of the Personal Data Protection Act of 2000 defines personal data as any piece of information that is related to an identified or identifiable natural person. According to Article 6 every natural person has the right to the protection of his or her personal data. According to Article 7 personal data can only be processed if – unless otherwise provided by law – the data subject has given his or her consent; the processing results from contractual

obligations of the data subject; the data processing is necessary to a system controller for performance of his or her obligations established in the law; the data processing is necessary in order to ensure that the public interest is complied with; or to fulfil functions of public authority; the data processing is necessary for complying with the fundamental human rights and freedoms of the data subject; and finally most importantly for biobanks, the data processing is necessary to protect vitally important interests of the data subject, including life and health. Article 10 Section (4) provides that personal data processing is permissible also for purposes other than those originally intended, provided it does not violate the rights of the data subject and is carried out for the needs of scientific or statistical research in accordance with other requirements laid down by the Act.

Sensitive data – some of which are stored and processed also by biobanks – are defined by Article 2 as “personal data which indicate the race, ethnic origin, religious, philosophical or political convictions, or trade union membership of a person, or provide information as to the health or sexual life of a person.” Simultaneously with the Personal Data Protection Act, Article 50 of the Medical Treatment Act provides that information on the medical treatment of patients is confidential data. According to Article 11 of the Data Protection Act the processing of sensitive personal data is prohibited, except if – among others – the donor has given his or her written consent for the processing of his or her sensitive data; a special processing of personal data is provided for by employment laws; person-

al data processing is necessary to protect the life and health of the data subject or another person, and the data subject is not legally or physically able to express consent; or sensitive data processing is necessary for the purposes of medical treatment, rendering health care services or administration thereof and distribution of medical remedies.

According to Article 15 the data subject has the right to obtain all information that has been collected concerning him- or herself, except if disclosure of such information is prohibited by law in the sphere of national security, defense and criminal law. The Medical Treatment Act provides for another exception from the general rule of access to one’s own data: first, it is only medical doctors who may provide the patient with his or her health information, and second, according to Article 41 doctors may withdraw information or provide incomplete diagnosis, if a complete prognosis would lead to the deterioration of the patient’s health status.

According to Article 16 of the Personal Data Protection Act data subjects may request that their personal data are supplemented or rectified, as well as that their processing be suspended or that the data be destroyed if the personal data are incomplete, outdated, false, unlawfully obtained or are no longer necessary for the purposes for which they were collected.

Article 28 allows the transfer of personal data to another state if that state ensures a level of data protection corresponding to the level of the data protection present in Latvia. This obligation does not have to be met if a system controller supervises the fulfill-

ment of protective measures and at least one of the following conditions is met: the data subject has consented to the data transfer abroad; the data transfer is required for the fulfillment of an agreement between the person concerned and the system controller; or for significant state or public interests, or for judicial proceedings; or for the protection of life and health of the data subject; or if the data transfer concerns public personal data or data accumulated in a publicly accessible register.

In the Latvian Genome Project Article 13 of the Human Genome Research Act declares that the Main Processor or the processor authorized by it has to give each tissue sample, DNA description, health description and genealogy a unique code once gene have been donated to the Genome Database. All data have to be replaced with a code enabling reverse identification of the gene donor, including the name, personal code and residence. The code has to be indicated on the prior written informed consent of the donor. The State Data Inspection has to approve the method of generating the codes. Gene donors themselves have the right to access their data stored in the Genome database and the right to genetic counselling.

Chapter 4 of the Human Genome Research Act is devoted to the issues of coding and decoding. According to Article 19 immediately after receipt of tissue samples, descriptions of DNA, state of health, and genealogies in the Genome Database, the Main Processor is to assign a unique code to each of these. The code has to consist of at least sixteen different symbols. Coding of the above sam-

ples and descriptions has to enable a reverse identification of the gene donor. The same provision emphasizes that the Main Processor has also to replace the gene donor's name, surname, personal identity number, and place of residence with a code. Within three days after data have been coded, the Main Processor has to forward the written consent together with the code indicated thereon to the State Population Genome Register. This document has to be the sole key for decoding information. The State Population Genome Register is permitted to decode data only for specific purposes, and only authorized persons are entitled to do the decoding. According to Article 20, decoding is allowed for the following purposes: destruction of tissue samples, DNA description, health description or genealogy; enabling access to data upon the request of the gene donor; renewal, supplementing or verification of health description, except if the donor prohibited this; issuing health description of a donor to his or her physician at the request of the physician, if the donor agreed to it.

8. STORAGE

According to Article 15 of the Human Genome Research Act it is the Main Processor that stores the coded tissue samples, DNA descriptions and health descriptions. The Genome Research Council may, if so requested by the Main Processor, grant permission for a limited number of tissue samples to be stored abroad, in case there are no appropriate research methods available in Latvia. The Main Processor has

the obligation to control tissue samples and to ensure that they cannot be used in a manner contrary to law. Whereas the Main Processor stores the coded tissue samples, the DNA and health descriptions, it is the State Population Genome Register that preserves the codes, personal information, and the written consents of donors.

Article 16 provides that the Genome Database may only be used for scientific research, for research on and treatment of the gene donor's diseases, for public health research, and for statistical purposes. The use of the Genome Database for any other purpose is prohibited.

9. SUPERVISION, COMPENSATION, PENALTIES

The Latvian genome Project is supervised by the State Data Inspection Agency according to Article 21 of the Human Genome Research Act. According to Article 22 the Central Medical Ethics Committee evaluates if genetic research, including the establishment and operation of the Genome Database is in compliance with ethical principles. As laid down in Article 23, individuals have the right to submit complaints for violations of the Human Genome Research Act to the State Data Inspection Agency, the decisions of which are subject to judicial review.

According to Article 29 of the Personal Data Protection Act the State Data Inspection supervises personal data protection under the jurisdiction of the Ministry of Justice. The State Data Inspection supervises the collection, coding, decoding, and processing of tissue samples, the descrip-

tions of DNA, health and genealogical data. The Central Medical Ethics Committee is entrusted with overseeing the ethical issues during the creation of the Genome Database and the data processing. According to Article 31 if the Personal Data Protection Act is violated, and as a consequence harm or losses occurred, the person having suffered damages has the right to receive commensurate compensation.

Genetic testing laboratories do not have to be certified in Latvia, however certificated laboratories have advantages when entering into contacts with medical insurance institutions. Therefore most genetic testing laboratories in Latvia are certificated. If a laboratory decides to be certificated, it has to meet certain quality criteria regulated by the Medical Treatment Act (1997) with amending Cabinet Regulations No. 133 (2001), No. 77 (2002), and the Regulation of the Ministry of Welfare No. 75 (2002).

10. PUBLIC DEBATE

A wide public debate on genetic screening and genetic research including also the issue of biobanks has taken place in Latvia between 2001-2002 during the discussion on the Human Genome Research Act. The debate was organised by those working on the Latvian Genome Project. The main findings of the debate can be summarised in four points: there is a public need for the development of genetic testing; when public and private interests are weighted against each other, the latter shall prevail; participation of individuals in genetic testing should be

entirely voluntary and shall be based on informed consent; and discrimination on the basis of genetic information shall be prohibited.⁶

Several workshops, conferences and discussions have been organised mainly by the Ministry of Welfare, Central Medical Ethics Committee on genetic screenings and the role and regulation

of biobanks, privacy, and data protection, and the legal framework for biomedical research.

At the same time it shall be noted that some scholars are dissatisfied with the level of public debate, especially with the lack of sufficient negotiations before the Human Genome Research Act's adoption.⁷

⁶ Line Matthiessen-Guyader (ed.), *Survey on national legislation and activities in the field of genetic testing in EU Member States*, Brussels: European Commission, 2005, 40. <http://ec.europa.eu/research/biosociety/pdf/bioethics-survey-test2106.pdf>

⁷ Aivita Putnina: *Population Genome Project in Latvia: Exploring the Articulation of Agency*, In: Judit Sándor: *Society and Genetic Information: Codes and Laws in the Genetic Era*, Budapest – New York: Central European University Press, 2003, 233-245.

II. FORENSIC BIOBANKS

1. DEFINITION OF FORENSIC BIOBANKS

The Latvian legislature did not give a definition of forensic biobanks, but laid down the objective of the DNA database established for forensic purposes, and defined a number of other terms from which the scope of the forensic DNA database can be derived. These include among others biological material, which is interpreted as “parts of human tissue or organs and body fluids which contain cells with deoxyribonucleic acid in the nuclei thereof [blood, saliva, semen, sweat, urine, soft tissue (such as muscles), bones, hair with their the outer root sheaths of the hair bulbs],” while biological traces are “biological material collected at the crime scene, at the place of residence of a missing person, from the victim, person arrested, suspected, or accused or clothes thereof, from a corpse, as well as from other types of material evidence.” As opposed to biological materials, also a computer-readable result, a so-called DNA profile of the genetic analysis of the DNA is kept in the database. Further information include the name, personal identity number, the

registration number of the crime, the name of the institution where the incident or item has been registered, and the amount and type of the biological material.⁸

The aim of the National DNA database according to Article 2 of the Act on its establishment, is the disclosure of criminal offences and the determination and regulation of the exchange of the results from DNA genetic analyses in international cooperation. Article 2 read in conjunction with Article 4 however seems to reveal that the National DNA database has several other objectives apart from crime prevention: according to this latter provision, beside DNA profiles and biological traces of suspects, accused persons, and convicts, also the profiles derived from unidentified bodies and missing persons are kept in the biobank.

2. RELEVANT LAWS

The main law in the field is the Act on the Establishing and Usage of the National DNA Database adopted on 17 June, 2004, signed by the President on 7 July, 2004, entering into force on 1 January,

⁸ Act on the Establishing and Usage of the National DNA Database, Article 1.

⁹ In original: DNS nacionālās datu bāzes izveidošanas un izmantošanas likums.

2005.⁹ The Act has in the meanwhile been modified on 9 March, 2006. The modification entered into force on 6 April, 2006.^{10,11}

Several lower pieces of legislation, i.e. decrees of the Cabinet of Ministers as delegated legislation, lay down detailed rules. Decree of the Cabinet of Ministers Nr. 319 of 10 May, 2005 provides for the details of the written consent to be acquired from the missing persons' biologically close relatives.¹² The exact method of sample taking from various groups of persons whose biological material may enter the National DNA database, are laid down in the Decree of the Cabinet of Ministers Nr. 620 of 23 August, 2005.¹³ The detailed rules on the determination of providing information are described by the Decree of the Cabinet of Ministers Nr. 698 of 13 September, 2005.¹⁴

3. MANAGEMENT

The Latvian forensic database is operated and managed by the Forensic Service Department of the State Police. At the same time the Forensic Service Department is also the holder of information resources – as laid down by

Article 6 of the National DNA database, while the holder of technical resources is the Information Centre of the Ministry of Interior according to Article 5. The Latvian National DNA biobank is a CODIS database.

4. SAMPLES AND SAMPLE TAKING, CONSENT

The detailed rules of sample taking from various groups of persons are laid down in the Decree of the Cabinet of Ministers Nr. 620 of 23 August, 2005. The police have the power to collect samples. DNA profiles can be obtained from crime scenes, suspects, convicts (of any crimes), volunteers, victims, and missing persons. From 1 August, 2007 samples may also be taken from convicts sentenced to imprisonment, and also from suspects at the pre-trial investigation stage. In case of suspects and convicted offenders, consent is not needed; coercion may be used, if necessary. Samples may be collected from crime scenes without any restrictions.

Decree Nr. 319 provides that whenever sample is taken from the missing persons' close relative, written consent

¹⁰ The amending law in original language can be found at <http://www.likumi.lv/doc.php?id=131055&from=off>

¹¹ Please find the consolidated version of the Act in original language at <http://www.likumi.lv/doc.php?id=90819>; while an unofficial English translation is available at http://www.ttc.lv/export/sites/default/docs/LRTA/Likumi/Development_and_Use_of_the_National_DNA_Database.doc.

¹² In original language: Kārtība, kādā pazudušu personu tuvi radinieki dod rakstveida piekrišanu salīdzināmo paraugu un ziņu iekļaušanai DNS nacionālajā datu bāzē un to apstrādei, available at <http://www.likumi.lv/doc.php?id=108033&from=off>

¹³ In original language: DNS nacionālajā datu bāzē iekļaujamo ziņu sniegšanas, kā arī bioloģiskā materiāla un bioloģiskās izcelsmes pēdu izņemšanas kārtība, available at <http://www.likumi.lv/doc.php?id=115159&from=off>

¹⁴ In original language: Noteikumi par DNS nacionālajā datu bāzē iekļautās informācijas sniegšanu, available at <http://www.likumi.lv/doc.php?id=116651&from=off>

needs to be acquired. Decree Nr. 620 prescribes written informed consent for sample taking from victims.

Samples may also be taken from children, if they are the biologically close relatives of missing persons. According to the Decree of the Cabinet of Ministers Nr. 319 of 10 May, 2005 reference samples from children may only be taken after his or her legal guardian's written consent has been obtained.

5. PURPOSE AND SCOPE OF COLLECTION

Should one read Article 2 of the Act on the National DNA database in conjunction with Articles 4 and 8, it is apparent that the objective of the National DNA database is the disclosure of criminal offences and the determination and regulation of the exchange of the results from DNA genetic analyses in international cooperation. In order to do that DNA profiles and biological traces of suspects, accused persons, convicts and also the profiles derived from unidentified bodies and missing persons are kept in the database. The data collection is not restricted to certain types of crimes, or to crimes above a certain gravity.

Article 8 provides that with the international agreements in line, also information on the DNA profiles of Latvians convicted in other states, foreigners having a permanent residence in Latvia, stateless persons and refugees are to be kept in the Latvian National DNA database.

6. ACCESS TO DATA AND SAMPLES

Chapter III, i.e. Articles 15-17 of the Act on the National DNA database are dealing with the access to information

included into the Latvian forensic biobank.

According to Article 15 the DNA profiles and information in the National DNA database are so-called "restricted access information." The only authority having full access to the database is the Forensic Service Department of the State Police. In line with the 2006 modification of the Act, Article 16 provides that only investigation authorities, with the consent of a prosecutor, the prosecution and the judiciary may have access to information stored in the forensic biobank, in case needed for a pre-trial criminal procedure, examination or adjudication of a criminal matter. In order to have access to information, the need for such information has to be substantiated. Online access is possible through the intranet of the Forensic Service Department of the State Police.

Article 16 of the Act on the National DNA database delegates the standard setting for the determination of the information to be provided and the amount thereof. The detailed rules are laid down in the Decree of the Cabinet of Ministers Nr. 698 of 13 September, 2005. The information to be provided are enumerated, such as name, ID number; circumstances of the crime; name, position and signature of the person responsible for the request, and the legal issue. Requests are recorded and kept for five years from the date of registration. Requests are answered in a written form within 15 days after receipt.

Article 17 of the Act on the National DNA database on international cooperation states that Latvia is participating in the international exchange of forensic DNA information in line with inter-

national agreements concluded by Latvia. The State Police International Cooperation Department coordinates the international exchange of DNA profiles. According to Article 17 Section (2) exchange of information with foreign law enforcement authorities may be carried out according to procedures laid down in international agreements.

7. STORAGE AND USE

Chapter II, i.e. Articles 9-14 of the Act on the National DNA database are dealing with the profiles and information to be included into the Latvian forensic biobank.

According to Article 9, once crime scene samples have been collected, the following information have to be included into the National DNA database: the registration number of the incident records or the number of the criminal case; the date when the crime has been committed; the name of the institution registering the case; the number and type of biological traces; and the DNA profile.

In relation to suspects, convicts and accused persons, the following pieces of information appear in the database according to Article 10: name; personal identity number (for foreigners and stateless persons instead of the ID number the date of birth); nationality; criminal case number; name of the institution from which the comparative sample has been withdrawn and the type of the sample; name of the person who has withdrawn the comparative sample; and the DNA profile.

Regarding unidentified bodies, corpses Article 11 prescribes that the following pieces of information be stored in the National DNA database: criminal

case number, or the registration number of the incident records or the number of the investigatory records file; the date when the body has been found; name of the institution responsible for the investigatory records or of the one where the criminal case is entered; the type of the biological material; and the DNA profile.

Article 12 lays down the pieces of information to be stored in the forensic databank in relation to missing persons. These are the name, and personal identity number of the missing person; name and personal identity number of biologically close relatives of the missing person; number of the investigatory records file or the criminal case number; name of the institution responsible for the investigatory records or of the one where the criminal case is entered; and the DNA profiles of biologically close relatives of the missing person. Sample taking from close relatives and inclusion of any of their data into the forensic database is only allowed after a free, written consent has been given. Decree of the Cabinet of Ministers Nr. 319 of 10 May, 2005 includes in an appendix the consent form to be filled out by the missing persons' biologically close relatives.

In case it is not possible to ascertain biologically close relatives of the missing person, or should they refuse to give the comparative samples, instead of the relatives' data the following information should be added: the list of those personal belongings of a missing person from whom the biological material has been obtained; the type of the biological material; and the DNA profile.

Not only the collection of samples, but also the timely provision of the Forensic Service Department with in-

formation are the responsibility of the investigative institutions, the Prisons Administration, the prosecution, the judiciary and medical institutions or medical practitioners, as laid down by Article 13.

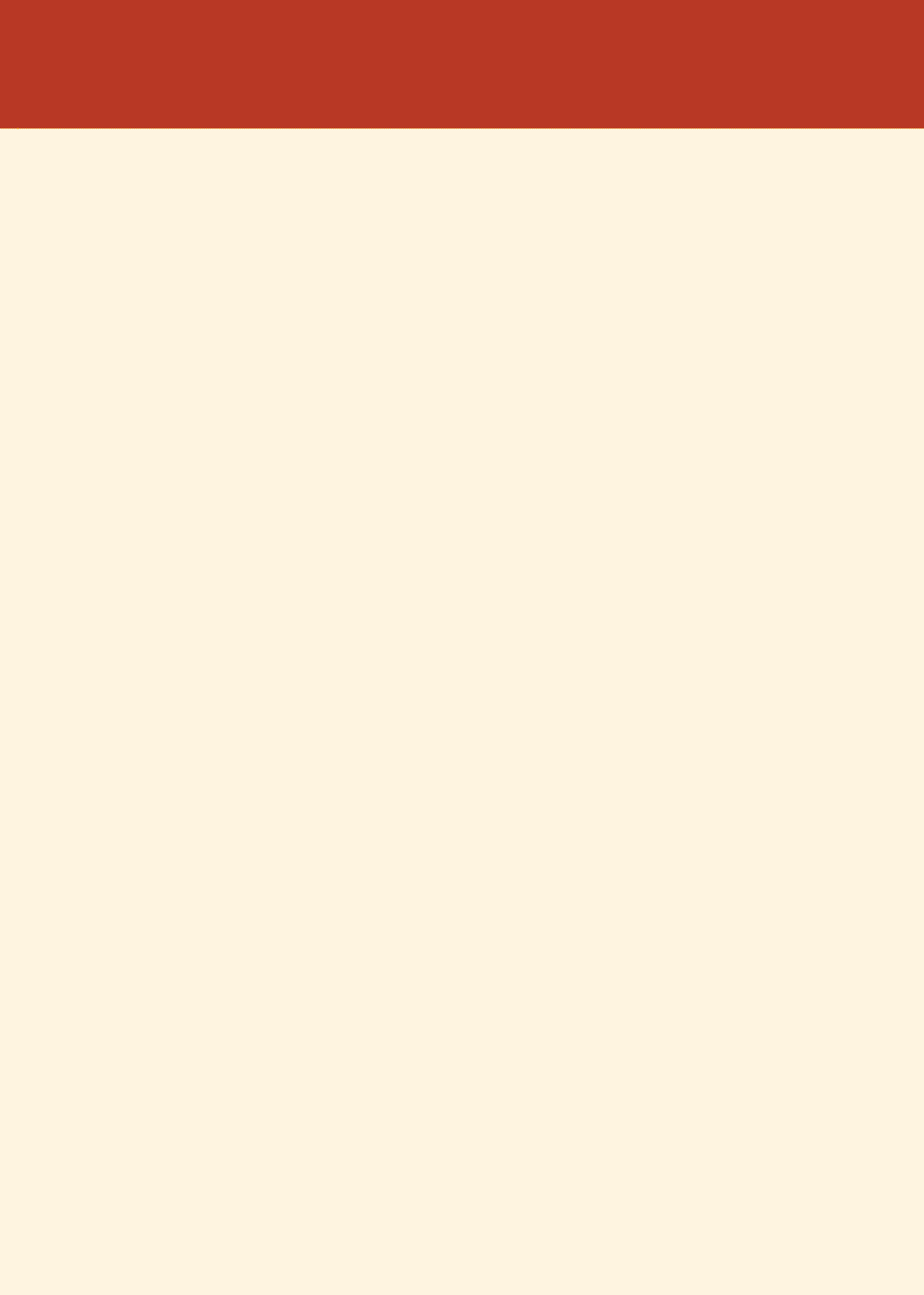
According to Article 14 the Forensic Service Department may request biological material, traces of biologic origin, DNA profiles and information from state and local government institutions free of charge.

Article 3 of the National DNA Database Act prohibits discrimination on the basis of data stored in the database, and the provision expressly sin-

gles out genetic discrimination among the forms of prohibited behaviours.

The same provision declares that comparative analysis of samples may only be carried out by certified experts of the State expertise institutions, furthermore these experts have to have at least a year long experience in the area.

According to Article 18 of the Act on the National DNA database data of suspects and convicts of any offence are registered in the national forensic database. The DNA profiles and information on anyone whose data have even been entered into the database are stored for a period of 75 years.





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