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The legal regulation of biobanks: National report: Lithuania

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THE LEGAL REGULATION
OF BIOBANKS

National Report:
Lithuania



CENTER FOR ETHICS AND LAW
IN BIOMEDICINE





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

As partners 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 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 fits into the series of country reports prepared by CELAB.

In the framework of the research, Enikő Demény has conducted several interviews with Lithuanian experts in the field and a related questionnaire has been filled out by

a number of Lithuanian scholars and practitioners. We are especially grateful to Dainius Characiejus, MD, PhD, Deputy Director for Research, and Kęstutis Sužiedėlis, MD, Head of the Institute of Oncology, Vilnius University; Dr. Eugenijus Gefenas, Chair of the Lithuanian Bioethics Committee; Dr. Jolita Supranavičiūtė, Chief Specialist of Law Division and Dr. Vaida Linartaite, Chief Specialist of Department of International Cooperation Division, State Data Protection Inspectorate; and Dr. Aurelija Žvirblienė, Head of Immunology Department, Institute of Biotechnology, Vilnius. We would also like to express our deep gratitude to experts Asta Čekanauskaitė and Irma Lukoševičienė from the Lithuanian Bioethics Committee.

The present paper summarizes the regulatory framework of biobanks in the Republic of Lithuania and focuses on the collection and analysis of legislation and regulation regarding the establishment, management and functioning of classical and forensic biobanks. Classical biobanks will be discussed 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 European Union laws, but it should be borne in mind that they are binding on Lithuania being a European Union Member State.

Budapest, 1 May, 2009

I. CLASSICAL AND POPULATION BIOBANKS

1. DEFINITION OF BIOBANKS

According to the definition laid down in Article 2 Section (8) of the Law on the Amendment of Human Tissue and Organ Donation and Transplantation of 25 March, 2004 No. IX-2078 a tissue bank is a public health care institution responsible for the procurement, preservation, storage and distribution of tissues and/or cells, as well as for other functions defined by law. Article 4 of the same Law provides that tissue banks can be established only by tertiary level public health care institutions and medical faculties.

2. RELEVANT LAWS

The primary legal regulation applicable to genetic testing is the Law on Ethics of Biomedical Research of 11 May, 2000, No. VIII-1679 which came into force on 1 January, 2001.¹ Genetic testing can be carried out for medical, scien-

tific or forensic purposes. Research projects that are involved in genetic testing of humans must be approved by the Lithuanian Bioethics Committee.²

Other relevant laws concerning biobanks in the Republic of Lithuania are the following: Law on Human Tissue and Organ Donation and Transplantation of 19 November, 1996, No. I-1626;³ Law on the Amendment of the Law on Human Tissue and Organ Donation and Transplantation of 21 December 1999 No.VIII-1484 as amended on 10 October, 2000 No. VIII-1985;⁴ Law on the Amendment of the Law on Human Tissue and Organ Donation and Transplantation of 25 March, 2004 No. IX-2078;⁵ Law on the Amendment of the Law on Human Tissue and Organ Donation and Transplantation of 19 October, 2006 No. X-867;⁶ and Law on the Rights of Patients and Compensation of the Damage to their Health of 3 October 1996,⁷ No. I-1562 as amended on 25

¹ English language version is available at http://www3.lrs.lt/pls/inter2/dokpaieska.showdoc_e?p_id=148740; In original language: http://www3.lrs.lt/pls/inter3/dokpaieska.showdoc_l?p_id=295871&p_query=&p_tr2=

² English language version is available at <http://bioetika.sam.lt/index.php?1710257197>; In original language: http://www3.lrs.lt/pls/inter3/dokpaieska.showdoc_l?p_id=33147

³ English language version is available at <http://bioetika.sam.lt/index.php?1710257197>; In original language: http://www3.lrs.lt/pls/inter3/dokpaieska.showdoc_l?p_id=286041&p_query=&p_tr2=

⁴ English language version is available at http://www3.lrs.lt/pls/inter3/dokpaieska.showdoc_l?p_id=112278; in original language available at

http://www3.lrs.lt/pls/inter3/dokpaieska.showdoc_l?p_id=93333&p_query=&p_tr2= and at http://www3.lrs.lt/pls/inter3/dokpaieska.showdoc_l?p_id=111308&p_query=&p_tr2=

⁵ In original language: http://www3.lrs.lt/pls/inter3/dokpaieska.showdoc_l?p_id=230908

⁶ In original language: http://www3.lrs.lt/pls/inter3/dokpaieska.showdoc_l?p_id=285790. Please find the consolidated English language version at www.transplantacija.lt/content/ftp/word/law_en.html

⁷ In original language: http://www3.lrs.lt/pls/inter3/dokpaieska.showdoc_l?p_id=31932&p_query=&p_tr2=

March, 2004.⁸ This latter Law does not cover reproductive cells, embryos and embryonic stem cells, fetal tissues, and with few exceptions blood components. The use of blood and its components is regulated by the Blood Donation Law adopted on 12 November, 1996, No. I-1611,⁹ as amended on 9 October, 2003.¹⁰ The Law on Health Care of 19 July, 1994, No. I-552 is another background piece of legislation.¹¹

Data protection standards are regulated by the Law on the Protection of Personal Data of 11 June 1996, No. I-1374¹² (hereinafter: Data Protection Law No. I-1374)¹³ amended several times on 12 March, 1998, 17 July, 2000, 22 January, 2002, 20 June, 2002,

21 January, 2003, 13 April, 2004 and most recently on 1 February, 2008.¹⁴

3. ESTABLISHMENT AND MANAGEMENT OF BIOBANKS

Biomedical databanking in Lithuania may be performed upon a double scrutiny. First, as biobanking typically involves biomedical research, approval has to be received from the Lithuanian Bioethics Committee or the Regional Biomedical Research Ethics Committee, as laid down in Article 12 of the Law on Ethics of Biomedical Research.¹⁵ Second, according to Article 10 of the Data Protection Law for collecting and storing medical data it is necessary to

⁸ In original language:

http://www3.lrs.lt/pls/inter3/dokpaieska.showdoc_l?p_id=31932&p_query=&p_tr2=

⁹ In original language:

http://www3.lrs.lt/pls/inter3/dokpaieska.showdoc_l?p_id=32919&p_query=&p_tr2=

¹⁰ In original language:

http://www3.lrs.lt/pls/inter3/dokpaieska.showdoc_l?p_id=220467&p_query=&p_tr2=

¹¹ In original language:

http://www3.lrs.lt/pls/inter3/dokpaieska.showdoc_l?p_id=319140&p_query=&p_tr2=

¹² English language version is available at <http://bioetika.sam.lt/index.php?1710257197>; In original language: http://www3.lrs.lt/pls/inter2/dokpaieska.showdoc_l?p_id=231799&p_query=&p_tr2=

¹³ In original language:

http://www3.lrs.lt/pls/inter3/dokpaieska.showdoc_l?p_id=159551&p_query=&p_tr2=

¹⁴ In original language:

http://www3.lrs.lt/pls/inter3/dokpaieska.showdoc_l?p_id=314940&p_query=&p_tr2=

¹⁵ See also Article 4 of the Law on Ethics of Biomedical Research on this requirement. Article 13 of the Law on Ethics of Biomedical Research determines the Lithuanian Bioethics Committee's establishment and competence. The Committee's composition and regulations are to be approved by the Ministry of Health. The Committee has legal personality and has the following tasks: it analyses the problems of bioethics, submits conclusions and proposals regulating problems of bioethics; annually reports to the Ministry of Health about its activities; reviews whether individual and public health care is in conformity with the principles of medical ethics; provides methodological assistance and consults medical ethics committees of health care establishments on the issues relating to their activities; represents Lithuania in international organizations; performs other functions provided for in its regulations; issues approvals for conducting biomedical research and undertake the ethical review of research and monitoring of the activities of Regional Biomedical Research Ethics committees; keeps records of biomedical research.

According to Article 14 of Regional Biomedical Research Ethics Committees are formed in the counties having universities. Their tasks include granting approvals when mandated this function by the Lithuanian Bioethics Committee; monitoring biomedical research for which they have given their approval; keeping record of biomedical research; making an annual report about their activities to the Lithuanian Bioethics Committee; and performing other functions mandated to them by the Lithuanian Bioethics Committee.

obtain a notification from the State Data Protection Inspectorate.

As to the former proceeding, Article 15 lays down further rules on the receipt and examination of applications. The sponsor or the principal investigator of biomedical research has to submit an application to the Lithuanian Bioethics Committee or the Regional Biomedical Research Ethics Committee. The documents must be examined and a reasoned approval or a refusal must be issued within 45 calendar days from the registration of the application, and after payment of all the fees for biomedical research expert examination. According to Article 16 the Lithuanian Bioethics Committee and the Regional Biomedical Research Ethics Committee not only issue approvals, but also have the right to invalidate them, in case there is evidence of non-compliance with the requirements of ethics of biomedical research. In such cases the sponsor, the principal investigator of biomedical research and heads of health care institutions where biomedical research was being conducted must ensure that biomedical research is immediately terminated. Appeal is possible to the Lithuanian Bioethics Committee against both a decision rejecting a request for approval, and against an invalidation of approval within 15 days from the receipt of such a decision. The latter decision of the second instance may be appealed in front of a court within 30 days from its receipt.

As to the latter process, two months before the intended commencement

of the data processing, the data controller is obliged to notify the State Data Protection Inspectorate. Within maximum two months the State Data Protection Inspectorate has to carry out prior checking and grant or refuse authorization to data processing, i.e. in the case under scrutiny, to operate a biobank. In case of a failure to make a decision, silence of the State Data Protection Inspectorate has to be interpreted as approval.

According to Article 34 of the Data Protection Law data controllers, i.e. private or public bodies determining the purposes of data processing (including biobanks) have to register in the State Register of Personal Data Controllers, which is administered by the State Data Protection Inspectorate. The current list of entities handling personal data can be found in a database available at the website of the State Data Protection Inspectorate.¹⁶

In practice, biobanks are governed by a research consortium set up at the institution, for example a clinic/hospital. There is no specific regulation on this aspect however.

4. PECUNIARY ASPECTS

Donors are not remunerated, and they can not receive any other benefits either, however according to Article 8 of the Law on Ethics of Biomedical Research before a research subject consents to a research, he or she has to be informed about the benefits of the prospective biomedical research for the subject him- or herself.

¹⁶ <http://db.ada.lt/searchResults.cfm> At the time of writing the present summary there have been no biobanks officially registered.

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

According to Article 5 of the Data Protection Law personal data may only be processed in case the data subject consented to it. According to Article 24 of the Data Protection Law, the following information have to be provided before obtaining consent: the identity of the data controller; the purpose of data processing; any other additional information, such as who the recipient of the data is and for what purposes the data of the data subject are disclosed; what personal data the data subject is supposed to provide; the right of the data subject to have access to his or her personal data and the right to request rectification of incorrect, incomplete and inaccurate personal data. According to Article 27 the data subject may withhold consent; in this case the data controller must immediately free of charge restrict the processing of personal data.

The more specific informed consent is regulated by the Law on Ethics of Biomedical Research. Article 6 about the protection and interests of research subjects states that biomedical research may only be undertaken after having obtained the free and informed consent of the subject. Article 7 Section (2) gives a specific safeguard for those who do not consent or withdraw their consent from biomedical research: they cannot be denied adequate health care. Article 8 stipulates that biomedical research can only be carried out after the research subject has given his or her written consent, i.e. had signed a consent form. Before consenting, the research subject has to

be given information about the aims, plan and method of the research and the decisions of the Lithuanian Bioethics Committee or an appropriate Regional Biomedical Research Ethics Committee, in a language easily understandable to the patient. The following information have to be provided for a consent to be informed in biomedical research: the benefits of the prospective biomedical research for the subject; the rights, foreseeable risks and inconveniences the research may cause to the subject, and the compensation available in the event of a research related injury; the right of the research subject to withdraw in writing his or her consent at any time, the consequences of discontinuing biomedical research; and the guarantees of confidentiality of the information.

According to Article 8 (2) the Lithuanian Bioethics Committee or the Regional Biomedical Research Ethics Committee has to decide before requesting the patient to consent, whether informed consent has to be obtained or is not necessary for the biomedical research to be carried out on tissues, organs, a foetus, cell or genetic material obtained from the donor for other purposes during medical interventions.

The Law on Ethics of Biomedical Research singles out a number of so-called vulnerable persons, whose willingness to volunteer in biomedical research may be unduly influenced, and awards them special protection. In case of biomedical research conducted with the participation of these persons, other requirements also have to be met. According to Article 7 in addition to the above safeguards, the institution carrying out the research has to prove that the trial objec-

tive can only be reached with the participation of vulnerable persons; the results of the biomedical research potentially produce real and direct benefit to the health of research subjects; and the research does not pose any risk to the health or life of a research subject. According to Article 5 vulnerable persons include individuals living with mental disabilities, minors, students if their participation in biomedical research is related to their studies, persons in nursing homes, active soldiers, personnel of health care institutions, where biomedical research is being conducted who are subordinated to the investigator. The list may be extended by the Lithuanian Bioethics Committee. The involvement of prisoners and other detainees however is expressly excluded by Article 5 Section (2).

In case of biomedical research conducted on minors under 18 years of age, Article 7 Section (2) provides that both parents or a legal representative, and the children's rights protection agency of a district or a city have to give consent. If the minor's parents are divorced, the consent of one of the parents or of the legal representative and of the district or city children's rights protection agency has to be obtained.

Article 7 Section (3) provides that the consent of a person with a mental disability has the right to give his or her free and informed consent to take part in a biomedical trial, and the consent must be certified by two witnesses and the head of a health care institution, where the biomedical research is carried out, furthermore the Hospital Medical Ethics Commission also has to approve.

According to Article 36 of the Data Protection Law, the State Data Pro-

tection Inspectorate is the supervising authority of data controllers, therefore this is the body that is checking informed consent forms before releasing a notification. Informed consent forms have to be approved by the National Bioethics Committee, too.

Samples can be taken from deceased people, too. There is an opt in system in Lithuania. According to Article 6 of the Law on Human Tissue and Organ Donation and Transplantation every legally capable person has the right to submit to a health care institution a written consent that his or her tissues and organs can be used for transplantation upon his or her death. Such a will is recorded in the personal medical card at the health care institution. The health care institution has to forward the information about the consent to the Register of Donors and Recipients of Human Tissues and Organs. There are no special rules on doing research on or storing genetic materials from deceased persons.

Beside the requirement of informed consent additional criteria have to be satisfied for a biomedical research including databanking to be permissible. According to Article 4 of the Law on Ethics of Biomedical Research the research has to have scientific and practical value; the donor's rights and confidentiality have to be protected; the sponsor of the research has to be insured against possible harms to the research subjects; and finally, as mentioned already when discussing the establishment of biobanks, the Lithuanian Bioethics Committee or the Regional Biomedical Research Ethics Committee has to approve of the research.

6. ACCESS TO DATA AND SAMPLES

The Lithuanian Data Protection Law makes clear in its first sentence that it sees data protection as an integral part of privacy.¹⁷ According to Article 2 of the Data Protection Law, personal data are “any information relating to a natural person – the data subject – who is identified or who can be identified directly or indirectly by reference to such data as a personal identification number or one or more factors specific to his or her physical, physiological, mental, economic, cultural or social identity.” Special categories of data include among others data concerning one’s health. According to Article 3 (1) records of data may only be stored for a definite purpose. According to the principle of proportionality phrased in Article 4 no one can collect, store or process more data or for a longer period of time than it is necessary for the approved purpose. Article 10 regulates data processing for the purposes of health care. Health data may only be processed by authorized health care professionals. A person’s health status is subject to the rules of professional secrecy as regulated by the Civil Code, the laws on the health care system and patients’ rights. According to Article 10 Section (2) of the Law on the Rights of Patients and Compensation of the Damage to their Health all the information on one’s health, diagnosis, prognosis, treatment, and other types of personal information shall be kept confidential, even after the death of the

patient. Article 12 of the Data Protection Law regulates the processing of personal data for scientific research purposes. Accordingly personal data can only be processed in scientific research projects if the data subject has given his or her consent.¹⁸ Without such a consent, personal data may only be processed if the State Data Protection Inspectorate has been notified and has carried out prior checking. The personal data have to be coded so that identification is impossible. Another requirement is that the data collected and stored for the purposes of scientific research may not be used for any other purposes. If the research does not require identifiable personal data, the data controller is obliged to provide to the data recipient data from which identification of a person is impossible. Finally, research results have to be made public together with the personal data only if the data subject consented to his or her personal data to be made public.

Chapter Five of the Data Protection Law lists the rights of the data subject. According to Articles 23-29 of the Data Protection Law, these include the right to know the identity of the data controller; the purpose of data processing; the right of the donor to access his or her own data, and to have the personal data rectified or destructed; furthermore the donor’s right to withhold consent of processing his or her data. The exercise of the right of the data subject to access his or her data as laid down in Article 25 is reinforced by Article 29

¹⁷ The Law states that it aims at protecting individuals’ right to privacy with regard to personal data processing. See Article 1 (1)

¹⁸ This is also a general data processing requirement laid down in Article 5 (1).

according to which the State Data Protection Inspectorate assists the data subject in the exercise of this right.

As to the transfer of data to foreign research institutes or clinics, Article 35 of the Data Protection Law is of relevance. Accordingly transfer of personal data to foreign countries is subject to an authorization from the State Data Protection Inspectorate, however the law grants a number of exemptions from this general rule. Data may be transferred without any further authorization if the data subject has consented to the transfer of data; or if data transfer is necessary for the conclusion or performance of a contract between the data controller and the data subject, or between the data controller and a third party concluded in the interests of the data subject; if transfer of personal data is necessary for the public interest, for the data subject's vital interest, or for the prevention or investigation of criminal offences; and finally laws may prescribe transfer of data without further checking by national authorities. In all other cases the State Data Protection Inspectorate is considering the safeguards for the protection of an individual's right to privacy as well for the protection and exercise of other rights of the data subject in the requesting state when rendering a decision about allowing or denying data transfer.

The following data are processed with the biological samples: a code, personal data, family information, health data.

A research institute (such as the Institute of Biotechnology) does not have the right to collect samples. Samples of biological materials can be collected only in clinical settings. The Institute for Biotechnology receives for certain research projects coded sample collections from clinical settings. After the research is carried out samples are destroyed.¹⁹

According to Article 9 of the Law on Ethics of Biomedical Research information gathered during biomedical research about the research subject's health, diagnosis, prognosis, treatment and other health related personal information is to be confidential and can only be made public if allowed and in the manner set forth in the Law on Patients' Rights and Compensation for Damage to Health. Such information is not regarded as confidential and may be made publicly available even without the consent of the donor if his or her identity remains undisclosed.

According to the Law on Insurance adopted on 18 September, 2003, No. IX-1737,²⁰ insurers are prohibited from requesting the policyholder, insured person and other persons in any form to provide them with data of genetic testing.

7. STORAGE

According to Article 4 of the Data Protection Law samples can be stored until the original purpose of the collection remains in effect. After that date personal data have to be destroyed.

¹⁹ Interview and questionnaire by Dr. Aurelija Zvirbliene, Head of Immunology Department, Institute of Biotechnology, Vilnius. Other similar institutes in Lithuania are: Institute of Oncology; Institute of Immunology; Institute of Experimental and Clinical Medicine; Institute of Biochemistry.

²⁰ In original language:

http://www3.lrs.lt/pls/inter3/dokpaieska.showdoc_l?p_id=340569&p_query=&p_tr2=

According to Article 24 of the same Law, the data controller has to take all technical and organizational measures to protect data. Coding is one of the measures. Article 5 of the Data Protection Law No. I-1374 provides that personal data be collected and stored in secure data records. The security and management of these is the responsibility of the data manager. Data are to be stored only for a definite purpose. Article 7 of the Data Protection Law No. I-1374 lists the scenarios when data have to be destroyed. These include situations where data are incorrect; or if it is prohibited to collect them; or when it is not needed by the manager of the data according to the functions it is performing.

Data according to Article 30 of the Data Protection Law have to be stored in a secure manner. This means that the data controller, in this case the biobank has to adopt organizational and technical measures that ensure the protection of personal data against any accidental or unlawful destruction, alteration, disclosure as well as against any other unlawful processing of data. These measures have to be laid down and specified in a written document or its equivalent. In case the data controller (i.e. a natural or legal person determining the purposes and means of data processing) authorizes a natural or legal person, but not an employee of the data controller – called data processor – to act on his, her or its behalf, this latter must also provide technical and organizational guarantees for the safety of data protection. The data controller also has to ensure in such cases that personal data are only processed by the data processor on his, her or its instruc-

tions. The relation between the data controller and the data processor has to be laid down in a written contract. The employees of the data controller and the data processor are obliged to keep the confidentiality of personal data. (Article 26 Section (5))

8. SUPERVISION, COMPENSATION, PENALTIES

The Data Protection Law lays down important rules concerning the supervision of biobanks, which are data controllers within the meaning of the law. According to Article 36 the implementation of the Law, just like the activities of data controllers, data processing, and respect for the rights of data subjects are supervised by the State Data Protection Inspectorate. An important exception should be noted with regard to the powers of the State Data Protection Inspectorate: it must not monitor processing of personal data in court proceedings, as laid down by Article 36 Section (3).

There are administrative penalties foreseen in case of contravention of the law. The Data Protection Authority prepares in such cases a protocol on administrative law violation and submits this protocol to the court. If there is a suspicion that crimes have been committed the State Prosecutor has to take action and apply the Criminal Code. According to Article 34 of the Data Protection Law the individual whose rights have been violated has to receive compensation for pecuniary and non-pecuniary damages. According to Article 33 data controllers and data processors in breach of the law are liable under the laws of Lithuania.

According to Article 11 of the Ethics

of Biomedical Research Law the sponsor and the principal investigator of biomedical research are liable for both pecuniary and non-pecuniary damages resulting from injury to the health of a donor or his or her death. In the latter event, the sponsor and the principal investigator of biomedical research must compensate for damage to the relatives in the order determined of the Law on Health Care. In order to ensure the paying of damages the same provision prescribes that in case if biomedical research is carried out on human

subjects, the sponsor and the principal investigator of biomedical research must be covered by third party insurance. The final provisions of the Biomedical Research Law also make sure that violation of the law is effectively sanctioned. According to Article 18 persons in breach of the law are liable. In case no damage to the donor's health has occurred, but biomedical research has been carried out without an approval or not in conformity with the law, the case shall be treated as an act of malpractice.

II. FORENSIC BIOBANKS

1. RELEVANT LAWS

In 1997, Lithuania was the first among the Baltic States, to conduct DNA tests for forensic purposes.²¹ Currently Article 156 Section (1) of the Criminal Procedure Code of the Republic of Lithuania (Law No. IX-785 of 14 March, 2002)²² gives authorization for carrying out genetic fingerprinting.

Chapter IV of the Law (Articles 66-77) is dealing with judicial and prosecutorial international cooperation. International requests may be satisfied on the basis of these provisions, mainly on the basis of Article 67. DNA can only be extracted and used for the investigation of specific criminal activities. According to Article 19 of the Police Law (Law No. VIII-2048 of 17 October, 2000) as amended,²³ police officers have the

right to take samples from convicts and suspects.

Examinations are carried out by the Lithuanian Police Forensic Research Centre and the forensic departments of the local police. Here among others DNA paternity tests and sample taking and analysis for criminal investigation purposes are mentioned.²⁴

Simultaneously with the incorporation of the Prüm Treaty into EU law, on 17 June, 2008, the Estonian and Lithuanian heads responsible for their national forensic biobanks, i.e. the Latvian National Police Commissioner, the Director of Estonian Forensic Science Institute and the Deputy Police Commissioner General signed a DNA exchange agreement.²⁵

The most recent Government Order No. 310 of 15 April 2009, entering into

²¹ http://ktc.policija.lt:82/lt/naujienos/lietuvos_policijos_kriminalistiniu_tyrimu_centro_raida.html

²² In original language: baudžiamojo proceso kodekso patvirtinimo, įsigaliojimo ir įgyvendinimo įstatymas, available at http://www3.lrs.lt/pls/inter3/dokpaieska.showdoc_l?p_id=319053

²³ In original language: Policijos Veiklos įstatymas, available at http://www3.lrs.lt/pls/inter3/dokpaieska.showdoc_l?p_id=325623&p_query=&p_tr2=

²⁴ Point 9.6.1. of the Order of the Police Chief No. 5-V-568 of 22 August, 2007, in original language: Ietuvos Policijos Generalinio Komisarų, įsakymas, dėl lietuvos policijos kinologijos centro reorganizavimo prijungimo prie Lietuvos policijos kriminalistinių tyrimų centro būdu, available at http://www3.lrs.lt/pls/inter3/dokpaieska.showdoc_l?p_id=303449&p_query=Identifikavimo%20dnr&p_tr2=2

²⁵ http://www.politsei.ee/?mid=5&mcid=11658&ctype=news_article&pageid=1094, www.policija.lt/get.php?f.3203

force on 1 May, 2009 intends to implement Council Decision 2008/615/JHA of 23 June 2008 on the stepping up of cross-border cooperation, particularly in combating terrorism and cross-border crime, i.e. the framework decision incorporating the main provisions of the Prüm Treaty into EU law.²⁶ As one can learn from the document, the Lithuanian Police Forensic Research Centre collects and manages DNA data systematically since 2003, and the investigation authorities greatly benefited from the advantages of the forensic biobank. Gradually Lithuania also started to participate in the international exchange of data. In October 2008 the United States Federal Bureau of Investigation supported the establishment of a CODIS database. As the Order notes, the Police Law and other pieces of Lithuanian legislation insufficiently regulate DNA sampling, testing, storage, processing, filing, storage, supply, use, and the exchange of information.

Currently, both the DNA register and also the legal framework governing DNA data collection, storage, processing, and exchange are missing, both of which would be needed for the creation of a national DNA database and for a meaningful exchange of information with other European Union Member States. The implementation of the Framework Decision will technically occur through amendments to the Police Law that will in the future regulate the details of the forensic biobank

in the making. The Forensic Science Research Centre will be designated as a national contact point.

2. MANAGEMENT

According to Article 5 (4) of the Data Protection Law personal data relating to a record of conviction, criminal acts or security measures in the course of crime prevention or investigation may only be processed by a state institution or agency. Other natural or legal persons may process such data if specified by law, provided that appropriate legal safeguards are established, and that these have been implemented for the protection of the legitimate interests of the data subject.

In line with the Data Protection Law, a state institution, the Biological Research Division of the Lithuanian Police Forensic Research Centre performs serological and DNA tests; identifies human biological samples and matches; and maintains DNA information. Research is conducted mainly on the basis of DNA analysis, and only a small part of research is still carried out by serological methods of analysis.²⁷ The technical realization of granting different levels of access rights to different groups of persons, is managed by the Lithuanian Police Forensic Research Centre's Information Technology Division.

According to the recent plans of the Government, the manager of the forensic biobank, and the national contact point under the Framework Decision

²⁶ In original language: Nutarimas dėl tarybos sprendimo 2008/615/tvr dėl tarpvalstybinio bendradarbiavimo gerinimo, visų pirma kovos su terorizmu ir tarpvalstybinio nusikalstamumu srityje, įgyvendinimo veiksmų plano patvirtinimo, available at

http://www3.lrs.lt/pls/inter3/dokpaieska.showdoc_l?p_id=342644&p_query=Identifikavimo%20dnr&p_tr2=2

²⁷ http://ktpolicija.lt:82/lt/struktura/skyriai/biologiniu_tyrimu_skyrius.html

2008/615/JHA will be the Lithuanian Police Forensic Research Centre.²⁸

3. SAMPLES AND SAMPLE TAKING, CONSENT

As already noted, Article 156 Section (1) of the Criminal Procedure Code of the Republic of Lithuania gives authorization for carrying out genetic fingerprinting. According to Section (2) force may be used, if necessary, once an authorization has been acquired by the public prosecutor.

Unidentified crime scene stains may be taken without any restrictions. As to sample taking from persons, the Lithuanian law differentiates between suspects and convicts. As to the former, samples may be taken without any limitations, however from the latter group of persons, sample may only be taken if the person convicted is at the same time falling into the former category, i.e. if they are suspected of having committed further crimes. Sample taking from mentally disabled persons is not permissible.²⁹ Samples may be taken of any suspects, i.e. from persons suspected with any crime.³⁰

4. PURPOSE AND SCOPE OF COLLECTION

As it is apparent from the Criminal Procedural Code and the Police Law, the

primary aim and purpose of the Lithuanian forensic biobank is assistance in national and international criminal investigations. Other objectives include search for missing persons, identifications unidentified corpses, and paternity tests.³¹

5. ACCESS TO DATA AND SAMPLES

One should certainly differentiate between access to data and samples, since DNA samples suspects and convicts are to be destroyed once a DNA profile has been derived therefrom.

The Lithuanian Police Forensic Research Centre authorizes database managers, scientists and police officers to have access – albeit different levels of access – to the DNA Database. Access rights are set by the Director of the Lithuanian Police Forensic Research Centre. Database managers and scientists may have access to all information while police officers can only check whether a certain individual's profile is included into the Database. Access rights are managed by the Lithuanian Police Forensic Research Centre's Information Technology Division.

Lithuania participates in the international exchange of DNA profiles via Interpol and Europol. Searches in the Lithuanian forensic database are performed upon requests received through National Interpol and Europol

²⁸ Government Order No. 310 of 15 April 2009

²⁹ Nathan Van Camp and Kris Dierickx, "National Forensic DNA Databases: Socio-Ethical Challenges and Current Practices in the EU," *European Ethical-Legal Papers* N° 9, Leuven, 2007, 63.

³⁰ DNA Databases to Assist with Criminal Investigations: Replies to the Questionnaire on National DNA Databases, Council of the European Union, 16 June, 2006, 9445/1/06, REV 1, 23.

³¹ Law No. 1V-232 of. 20 June, 2006, In original language: įsakymas Dėl Ieškomojų asmenų, neatpažintų lavonų ir nežinomų bejėgių asmenų žinybinio registro, available at: http://www3.lrs.lt/pls/inter3/dokpaics-ka.showdoc_l?p_id=279249&p_query=Identifikavimo%20dnr&p_tr2=2

Bureau or police liaison officers. Requests can be made both electronically and via a paper-based version. The Lithuanian Police Forensic Research Centre is technically equipped to receive communications through electronic means.³²

For a search for matches a request has to be issued by a pre-trial investigator, a prosecutor or a judge. For an international search to be conducted, a request from the National Interpol or Europol Bureau, or police liaison officer is to be obtained.³³

Once a match is found, the following information are provided: type of offence, reference number of a criminal case, name and identification number, institution that submitted the DNA sample to the database.³⁴

6. STORAGE

DNA samples of crime suspects and convicted offenders must be destroyed immediately after having been analysed and once the related DNA profiles have been stored into the database.

DNA profiles which had been derived from unidentified crime scene stains may be kept without any limitations in time. As to suspects and convicts, their DNA profiles may be kept for up to one hundred years, which is the maximum time limit of the so-called "long-term storage" defined by the rules on electronic document management (Order No. V-12 of 11 January 2006),³⁵ or alternatively until ten years after the passing away of the individual.

³² DNA Databases to Assist with Criminal Investigations: Replies to the Questionnaire on National DNA Databases, Council of the European Union, 16 June, 2006, 9445/1/06, REV 1, 30.

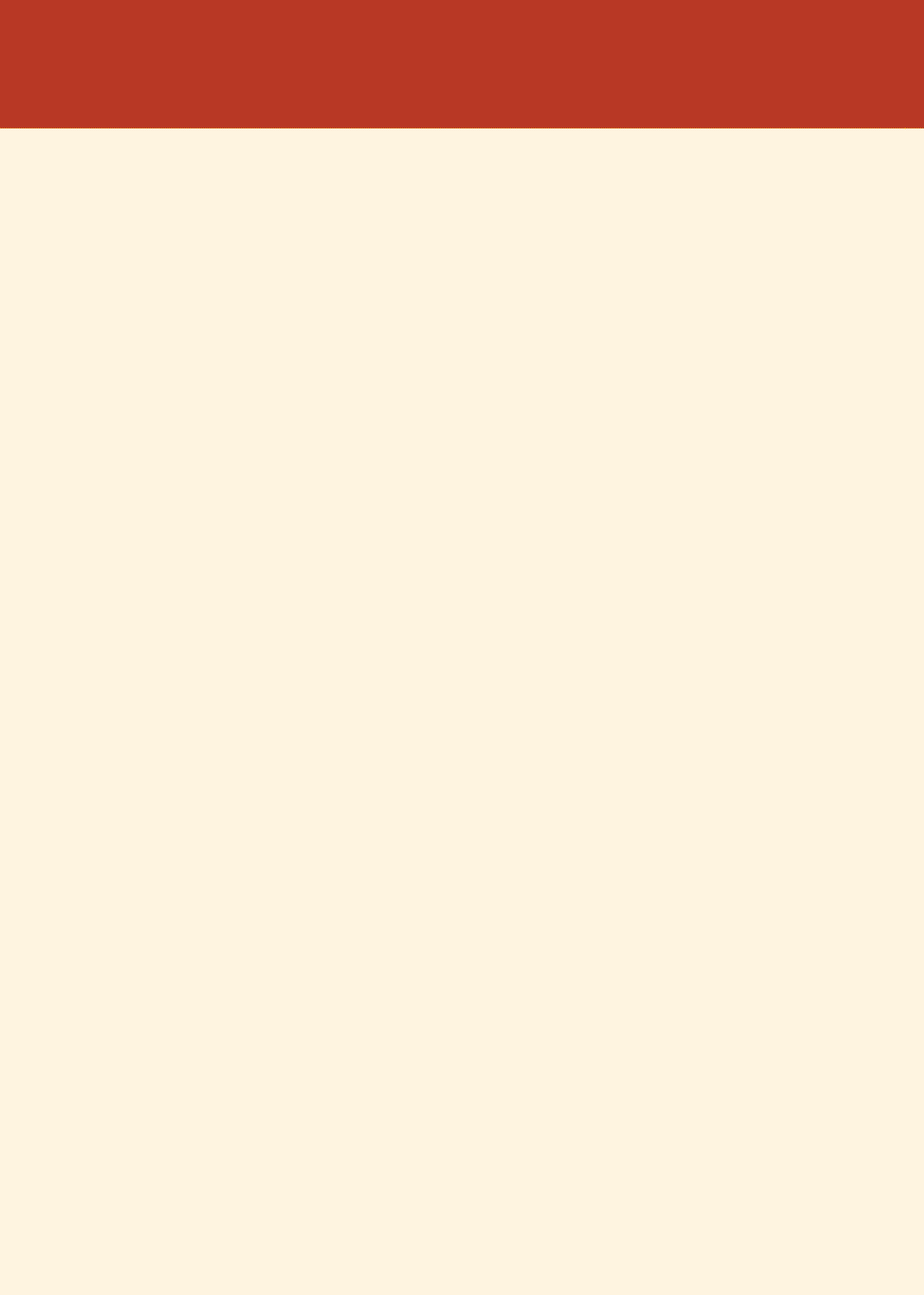
³³ *Id.*, 23.

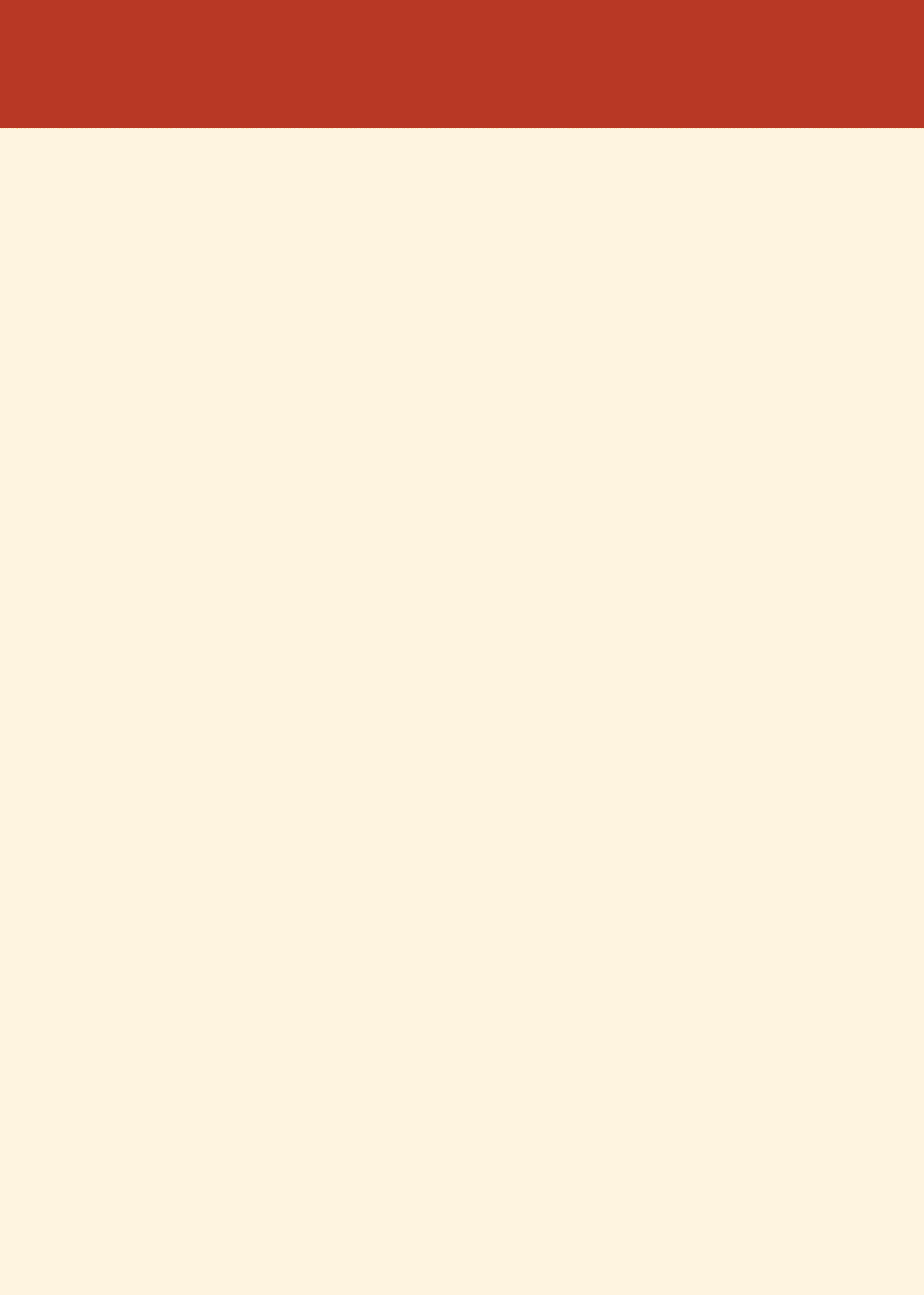
³⁴ *Id.*, 26.

³⁵ In original: Dėl Elektroninių dokumentų valdymo taisyklių patvirtinimo, available at:

http://www3.lrs.lt/pls/inter3/dokpaieska.showdoc_l?p_id=269626&p_query=%22100%20met%F8%22%20%2210%20met%F8%22&p_tr2=2

³⁶ Nathan Van Camp and Kris Dierickx, "National Forensic DNA Databases: Socio-Ethical Challenges and Current Practices in the EU," European Ethical-Legal Papers N° 9 National Forensic DNA Databases, Leuven, 2007, 64.







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