

No.12

CELAB PAPER SERIES

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JUDIT SÁNDOR

PETRA BÁRD

THE LEGAL REGULATION
OF BIOBANKS

National Report: Slovenia



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CENTER FOR ETHICS AND LAW
IN BIOMEDICINE





Editors: Judit Sándor and Petra Bárd

© April 2010

Center for Ethics and Law in Biomedicine (CELAB)

ISSN 2074-4498

ISBN 978-963-88538-4-4

Address: 1051 Budapest Nádor u. 9. Hungary

Telephone: +36-1-472-3403

Fax: +36-1-354-1599

E-mail: celab@ceu.hu

Website: <http://www.ceu.hu/celab>

Design and layout: Zsolt Sándor

Printed in Hungary by FOM kft.

The research behind the publication has been supported by GeneBanC, a specific targeted research project on 'Genetic Bio and Databanking: Confidentiality and Protection of Data. Towards a European Harmonisation and Policy' and by Tiss.EU, a research project on the 'Evaluation of Legislation and Related Guidelines on the Procurement, Storage and Transfer of Human Tissues and Cells in the European Union - an Evidence-Based Impact Analysis' both funded by the European Commission as part of the 6th and 7th Framework Programmes respectively.



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Judit Sándor, Petra Bárd

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

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 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 is one in the series of country reports prepared by CELAB.

We would like to express our gratitude to multiple scholars from the Slovenian juris-

diction. We would like to thank Primož Gorkič, Professor at the University of Ljubljana Faculty of Law, Assistant Professor Primož Rožman, MD PhD, Associate Professor at the Medical Faculty, University of Ljubljana and Head of the Immunohaematology Department and Dragoslav Domanović, MD PhD, Head of the Blood Supply Department of the National Blood Transfusion Centre of Slovenia, Ljubljana. Furthermore we are also grateful to Marija Meznarič-Petruša, MD, Assistant Professor at the Institute of Anatomy of the University of Ljubljana. We very much appreciate the help of Edita Mavčič who did the thorough translations and we are also grateful to Natasa Kozamernik from the Ministry of Health for making our visits to Slovenian biobanks smooth and effective. From the Slovenian General Police Directorate, Forensic Science Center at the Ministry of Interior Janez Golja kindly filled our questionnaire, while Katja Drobnič, Ph.D., Quality Manager and Aleksander Regent, Head of the Biological Examination Division of the General Police Directorate Forensic Science Center served us valuable information as to forensic biobanking in their country. We also owe special thanks to Dr. Judit Schvéger for her support in writing this report.

Budapest, 1 April 2010

I. CLASSICAL AND POPULATION BIOBANKS

1. DEFINITION OF BIOBANKS

There is no special regulative framework on the establishment and management of biobanks in Slovenia, however the country has adopted several legislative measures that consist of constitutional provisions, international conventions, laws, regulations, codes of practice and so forth, which are potentially applicable to biobanks.

Although in Slovenia there is no specific law on biobanks or on genetic data, the Act on the quality and safety of human tissues and cells intended for treatment (hereinafter referred to as Human Tissue Act)¹ and the ministerial regulations on the execution of the previous act contain rules concerning the establishment of tissue and cell banks. According to Article 4 of the Human Tissue Act, "tissue bank" shall mean a unit of facilities for the storage of tissues and cells (Article 20); the same Article also sets forth that "tissue and cell establishment" shall mean a public health institution or unit of a hospital unit or other legal persons, where activities of processing, preservation, storage, dispensing or distribution of tis-

suess and cells takes place; furthermore it states that a tissue and cell establishment may be responsible for the procurement and testing of tissues and cells (Article 21).

2. RELEVANT LAWS

Rules applicable to biobanks, research conducted on cells and tissues, and anonymisation requirements cannot be found in one single comprehensive piece of legislative document, however a number of national legislative acts and international instruments are governing the field.

After the Republic of Slovenia has become an independent and sovereign state in 1991, many of its legal fields have been subjected to new legislative regulations. Furthermore, the newly adopted legislative measures intend to enshrine and follow up principles and norms covered by international conventions. Such legislative practice was also applied in the field of biomedicine. Slovenia signed and made no reservations to the Oviedo Convention on 4 April 1997, whereupon it was ratified by

¹ Zakon o kakovosti in varnosti človeških tkiv in celic, namenjenih za zdravljenje (ZKVČTC), Uradni list RS, št. 61/2007, 10/07/2007, 08529-08536, 09/08/2007; (MNE(2008)54360). Available in Slovenian at <http://www.uradni-list.si/1/objava.jsp?urlid=200761&stevilka=3297> In English: Law on quality and safety of human tissues and cells intended for treatment, Official Gazette of RS, No: 61/2007, 10/07/2007, Page: 08529-08536, Entry Into Force: 09/08/2007; Reference: (MNE (2008) 54,360).

the National Assembly on 5 November 1998 and the document entered into force on 1 December 1999².

In accordance with Article 8 of the Constitution of the Republic of Slovenia³, laws and other regulations must comply with generally accepted principles of international law and with treaties that are binding on Slovenia. Furthermore ratified and published treaties shall also be applied directly, therefore as of its enforcement the Convention became part of the Slovenian internal law and can be applied directly in all legal procedures. It is also worth mentioning that the Convention influenced a number of national legislation in the field of biomedicine.

Since Slovenia has not adopted any specific legislation concerning biobanks, the relevant legal regulation consists of generally applied provisions of legal instruments such as legislation in relation to data protection or patient rights as well as certain pieces of legislation concerning the regulation of transplantation along with rules on tissues and cells. In relation to the latter,

it is also worthwhile to mention that Slovenia has already transposed the relevant pieces of European directives in the respective legal domain into the national law and the area that is most comprehensively covered by national legislation is the procurement and storage of human tissues and cells for medical purposes. The main legal instrument in this field is the Act on the quality and safety of human tissues and cells intended for treatment that is transposing Commission Directive 2006/17/EC of 8 February 2006 implementing Directive 2004/23/EC of the European Parliament and of the Council as regards certain technical requirements for the donation, procurement and testing of human tissues and cells. In addition to the above, the Ministry of Health also adopted several ministerial regulations on the implementation and execution of the Human Tissue Act, such as the Regulation setting the standards for licensing an establishment for procurement of human tissues and cells (hereinafter referred to as Tissue Establishment Regulation)⁴

² Zakon o ratifikaciji Konvencije o varstvu človekovih pravic in dostojanstva človeškega bitja v zvezi z uporabo biologije in medicine (Konvencija o človekovih pravicah v zvezi z biomedicino) in Dodatnega protokola o prepovedi kloniranja človeških bitij h Konvenciji o varstvu človekovih pravic in dostojanstva človeškega bitja v zvezi z uporabo biologije in medicine (MVCPCB), Stran 277. Uradni list RS, št. 70/1998 z dne 16. 10. 1998. In English: Law on ratification of the Convention on 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) and the Additional Protocol on the Prohibition of Cloning Human Beings to the Convention on the Protection of Human Rights and Dignity of the Human Being with regard to Application of Biology and Medicine (MVCPCB), 277th page. <http://www.uradni-list.si/1/objava.jsp?urlimpid=199842>

³ Ustava Republike Slovenije /URS/, Ur.l. RS, št. 331/1991-I, Spremembe: Ur.l. RS, št. 42/1997, 66/2000, 24/2003, 69/2004, 69/2004, 69/2004, 68/2006. In English: Constitution of the Republic of Slovenia, Official Gazette. 33/91-I, amended in 42/97, 66/2000, 24/03, 69/04, 68/06. <http://www.us-rs.si/0-sodiscu/pravna-podlaga/ustava/?lang=1>

⁴ Pravilnik o pogojih za izdajo dovoljenja za opravljanje dejavnosti preskrbe s človeškimi tkivi in celicami, Ministrstvo za zdravje, Uradni list RS, št. 70/2008 z dne 11. 7. 2008, Available in Slovenian at <http://www.uradni-list.si/1/objava.jsp?urlid=200870&stevilka=3033> In English: Regulation setting the standards for licensing an establishment for procurement of human tissues and cells, Ministry of Health, Official Gazette of RS, No.: 70/2008.

and the Regulation on the traceability of human tissues and cells as well as products and materials that come in touch with tissues and cells (hereinafter referred to as Traceability Regulation)⁵, also the Regulation on donation and procurement of human tissues and cells⁶ (hereinafter referred to as Human Tissue Procurement Regulation) and Regulation on the import/export and input/output proceedings applicable to human tissues and cells⁷ (Hereinafter referred to as Human Tissue Import/Export Regulation), Regulation on the reception, processing, storage, release and distribution of human tissues and cells⁸ (hereinafter referred to as Human

Tissue Processing Regulation) as well as the Regulation on histovigilance⁹.

Certain pieces of legislation concerning transplantation and its related domains are also worthwhile to mention, such as the Act on the removal and transplantation of human body parts for therapeutic purposes (hereinafter referred to as Transplantation Act)¹⁰ and the Health Services Act¹¹ which is deemed as a background legislation for medical researches involving human biological materials.

In addition to the above mentioned legislations the Personal Data Protection Act¹² is also relevant in the respective legal domain. Biobanks contain not only biological samples but

⁵ Pravilnik o sledljivosti človeških tkiv in celic ter izdelkov in materialov, ki prihajajo v stik s tkivi in celicami, Ministrstvo za zdravje, Uradni list RS, št. 70/2008 z dne 11. 7. 2008. Available in Slovenian at <http://www.uradni-list.si/1/objava.jsp?urlid=200870&stevilka=3036> In English: Regulation on the traceability of human tissues and cells as well as products and materials that come in touch with tissues and cells, Ministry of Health, Official Gazette of RS, No.: 70/2008.

⁶ Pravilnik o darovanju in pridobivanju človeških tkiv in celic, Ministrstvo za zdravje, Uradni list RS, št. 70/2008 z dne 11. 7. 2008. Available in Slovenian at <http://www.uradni-list.si/1/objava.jsp?urlid=200870&stevilka=3038> In English: Regulation on donation and procurement of human tissues and cells, Ministry of Health, Official Gazette of RS, No.: 70/2008.

⁷ Pravilnik o pogojih in postopku za uvoz in izvoz ter vnos in iznos človeških tkiv in celic, Ministrstvo za zdravje, Uradni list RS, št. 70/2008 z dne 11. 7. 2008. Available in Slovenian at <http://www.uradni-list.si/1/objava.jsp?urlid=200870&stevilka=3037> In English: Regulation on the import/export and input/output proceedings applicable to human tissues and cells, Ministry of Health, Official Gazette of RS, No.: 70/2008.

⁸ Pravilnik o sprejemu, obdelavi, shranjevanju, sprostitvi in razdeljevanju človeških tkiv in celic, Ministrstvo za zdravje, Uradni list RS, št. 70/2008 z dne 11. 7. 2008. Available in Slovenian at <http://www.uradni-list.si/1/objava.jsp?urlid=200870&stevilka=3034> In English: Regulation on the reception, processing, storage, release and distribution of human tissues and cells, Ministry of Health, Official Gazette of RS, No.: 70/2008.

⁹ Pravilnik on histovigilance, Ministrstvo za zdravje, Uradni list RS, št. 70/2008 z dne 11. 7. 2008. Available in Slovenian at <http://www.uradni-list.si/1/content?id=87589> In English: Regulation on histovigilance, Ministry of Health, Official Gazette of RS, No.: 70/2008.

¹⁰ Zakon o odvzemu in presaditvi delov človeškega telesa zaradi zdravljenja (ZOPDCT), Uradni list RS, št. 12/2000 z dne 11. 2. 2000, 61/2007. In English: Act on the removal and transplantation of human bodyparts for therapeutic purposes, Official Gazette of RS, No.: 12/2000, 67/2007.

¹¹ Zakon o zdravniški službi (ZZdrS), Ur.l. RS, No.:98/99 and 67/02 Available in Slovenian at: <http://www.uradni-list.si/1/objava.jsp?urlid=199998&stevilka=4618> In English: Health Services Act, Official Gazette of RS, No.: 98/1999, 67/2002.

¹² Zakon o varstvu osebnih podatkov (ZVOP-1), Ur.l. RS, No.:59/99, 57/01, 59/01 and 52/02 Available in Slovenian at: <http://www.uradni-list.si/1/objava.jsp?urlid=200486&stevilka=3836> In English: Personal Data Act, Official Gazette of RS, No.: 59/1999, 57/2001, 59/2001.

also personal data about the donor of the biological material such as data related to health and genetic information. Therefore one of the main legal instruments on their regulations is the Data Protection Act 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.

According to Article 38 of the Slovenian Constitution the protection of personal data shall be guaranteed and the use of personal data contrary to the purpose for which it was collected is prohibited. The collection, processing, designated use, supervision, and protection of the confidentiality of personal data shall be provided by law.

The Personal Data Act also sets out that personal data that are being processed must be adequate and in their extent appropriate in relation to the purposes for which they are collected and further processed. In line with point 19, Article 6 of the Personal Data Act sensitive personal data shall mean data on racial, national or ethnic origin, political, religious or philosophical beliefs, trade-union membership, health status, sexual life, the entry in or removal from criminal record or records of minor offences that are kept on the basis of a statute that regulates minor offences; biometric characteristics are also sensitive personal data if their use makes it possible to identify an individual in connection with any of the aforementioned circumstances. In relation

to biometrics characteristics the Act (Article 6, point 21) also sets forth that it shall be any physical, physiological and behavioural characteristics which all individuals have but which are unique and permanent for each individual specifically and which can be used to identify an individual, in particular by the use of fingerprint, recording of papillary ridges of the finger, iris scan, retinal scan, recording of facial characteristics, recording of an ear, DNA scan and characteristic gait.

In addition to the Human Tissue Act and the Transplantation Act as special legislative measures on the execution of tissue bank, the establishment of such institutions, the collection, processing as well as storage of genetic information also fall under the general provisions on patient rights. The Patient Rights Act¹³ shall be deemed as an important legal source in the field of patient right in the country and it was drafted in the light of the provisions of the Oviedo Convention. The act entered into force on 26 February 2008 and sets forth the rights of patients to voluntarily decide on giving consent to therapeutic interventions and research as a user of health care services as well as provisions on medical decisions about patients unable to consent. The Act shall also be deemed as a background legislative act with regard to the patient's informed consent to medical treatment or procedure as well as to the right to privacy in medical procedures.

In addition to the aforementioned legislative framework, in terms of clinical trials the Slovenian Code of Medical

¹³ Zakon o pacientovih pravicah, Uradni list RS, št. 15/2008, Available in Slovenian at <http://www.uradni-list.si/1/objava.jsp?urlid=200815&stevilka=455> In English: Patients Right Act, Official Gazette, 15/2008.

Deontology, formulated by the assistance of the Slovenian National Medical Ethics¹⁴ Committee (NMEC), is also worthwhile to mention. The Code of Medical Deontology contains provisions on ethical conduct of biomedical research on human subjects (Articles 47-51.)

Furthermore the Slovenian Penal Code also proves to be important since Article 154 of the Code sets out legal provisions on the misuse of personal data. According to the Penal Code “[W]hoever contrary to the statute uses personal data, which may be kept only on the basis of the statute or on the basis of the personal consent of an individual to whom the personal data relate, shall be punished by a fine or by imprisonment of not more than one year”. Moreover Article 191 Sections (1)-(4) of the Penal Code also declare that any physician, who unlawfully removes a part of a human body or implants or removes such a part before the legal certification of death or without having obtained the informed consent of the donor and/or recipient is punishable with up to six months to five years imprisonment. The same punishment is applicable to any other person who unlawfully deals for financial gain with parts of a living or dead person for transplantation purposes.

Additionally it also should be mentioned that the Slovenian National Medical Ethics Committee is entitled to review and authorize clinical researches on humans and it also adopts posi-

tion papers on ethical issues in relation to medical treatment and research.

3. ESTABLISHMENT AND MANAGEMENT OF BIOBANKS

As it is mentioned above Article 4 of the Human Tissue Act lays down the definition of a tissue bank and tissue and cell establishment. According to Article 5 of the same Act, the Agency of Medical Products and Devices for the Slovenian Republic or JAZMP¹⁵ shall authorize any activity and implement supervisory inspections and control measures with regard to the management of tissue and cell as well as activities of production, testing, processing, preservation, storage, allocation and distribution of tissues and cells intended for human use. According to Article 6 the Authority is vested the competency to grant license for the establishment of tissue banks in order to ensure that the production, testing, processing, preservation, storage, allocation and distribution of tissues and cells are performed by appropriately qualified and experienced professionals, and that the management of tissues and cells is performed as a public service in public health care institutions.

According to Article 12 of the Human Tissue Act the Institute for transplantation of Organs and Tissues of the Republic of Slovenia or with its abbreviated name Slovenia-transplant¹⁶, shall keep a central information system for

¹⁴ Komisija Republike Slovenije za medicinsko etiko (KME), <http://www.kme-nmec.si/>

¹⁵ Javna agencija Republike Slovenije za zdravila in medicinske pripomočke (Agency for Medical Products and Devices of the Republic of Slovenia) <http://www.jazmp.si/index.php?id=56>

¹⁶ Slovenija-transplant or Zavod RS za presaditve organov in tkiv, (Slovenian-transplant, Institute for transplantation of Organs and Tissues of the Republic of Slovenia) <http://www.slovenija-transplant.si/>

transplantation activities, including a register of activities carried out in accordance with the Human Tissue Act and with the Transplantation Act. Slovenia-transplant is the central national institution which links together all the institutions working on the field of transplantation.

The central information system also includes the data on the (1) type and quantity of the procured, tested, processed, stored, allocated, distributed or otherwise removed human tissues and cells as well as (2) on the origin and (3) destination of the tissues and cells intended for therapeutic purposes in accordance with the requirements determined by the Tissue Establishment Regulation. In line with Article 7 of the latter regulation, Slovenia-transplant shall coordinate the allocation of tissues and cells for allogeneic use that are on the donation waiting lists for transplantation.

In addition to current reports, tissue and cell establishments shall submit to Slovenia-transplant a publicly available annual report on the activities carried out on the basis of the Human Tissue Act.

Slovenia-transplant shall also establish and maintain a publicly accessible register of tissue and cell establishments specifying the activities for which they have been accredited and licensed. Nevertheless Slovenia-transplant may delegate the maintenance of particular registers to an accredited tissue and cell establishment.

With regard to data protection of genetic information the donor center, the tissue and cell establishment and the

users of tissues and cells shall enter with Slovenia-transplant into an agreement in writing on the method of conveying the data as well as on data protection and safeguarding against access of unauthorized persons.

In line with the above mentioned rules the operation of the Neuromuscular Biobank of the University of Ljubljana, Medical Faculty, Institute of Anatomy¹⁷ is worthwhile to mention. The Neuromuscular Biobank is a population-based and disease-focused (muscle diseases) biobank seated in Ljubljana and it is considered as a national collection of genetic information in the respective domain. The Neuromuscular Biobank has conducted its research activities in collaboration with the Institute of Genetics, the Institute of Clinical Neurophysiology and the University Paediatric Clinic Ljubljana, as well as international centres for neuromuscular diseases. Additionally to the Neuromuscular Biobank of the University of Ljubljana, Educell a private company dealing with cell therapy and tissue engineering was, in November 2008, the first company to gain the status of Tissue Establishment from the Agency for Medicinal Products and Medical Devices of the Republic of Slovenia¹⁸.

4. PECUNIARY ASPECTS

According to Article 13 of the Human Tissue Act in line with European and Slovenian ethical principles and legislation, as well as taking account of the related provisions of the Oviedo Con-

¹⁷ <http://www.eurobiobank.org/en/partners/description/ljubljana.htm>

¹⁸ <http://www.educell.si/en/-about-us/news-66317/press-release-193025/>

vention, human tissues and cells may only be donated on an unpaid, voluntary basis, regardless of the purpose of the medical treatment (both for allogeneic and autologous treatment). Additionally Section (2) of Article 13 also declares that the advertising of the donation of tissues and cells for financial gain or other benefit is also prohibited.

In order to ensure the above mentioned principles on voluntarily and free-of-charge donation, Article 4 of the Human Tissue Donation Regulation also sets out that voluntary and unpaid donation is encouraged through the application of the measures in accordance with Articles 5 and 13 of the Human Tissue Act. The invoked provisions of the Human Tissue Acts lay down the obligations and duties of the Agency for Medical Products and Devices responsible for the supervision of tissue establishments. The results of the implementation of these measures are reported by Slovenija-transplant to the Ministry of Health that in turn keeps informing the European Commission thereof on a three year basis.

Besides the Human Tissue Act the Transplantation Act also sets forth rules on the prohibition of pecuniary compensation of donation. Therefore Article 4 of the Transplantation Act declares that no payment or any other property benefit shall be given or accepted for procured human body parts. However this restriction shall not apply to the payment for medical and technical services relevant for the removal and the transplantation. It is also permissible to indemnify the donor for the loss of earning and to cover any other expenses incurred by the donation of the organ or the tissue.

The donors shall be entitled to receive free medical treatment after the intervention as well as an adequate compensation for any unexpected severe damage that occurred to health as a direct consequence of the removal.

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

The Slovenian Constitution lays down the fundamental principles in relation to the right to the personal dignity and inviolability of the individual's physical and mental integrity. With the view to free and voluntarily given consent to therapeutic and medical treatments Article 51 of the Constitution declares that no one may be compelled to undergo medical treatment except in cases provided by law.

As it is mentioned above, the Human Tissue Act and its detailed implementing regulations such as the Human Tissue Donation Regulation cover mainly the procurement of human tissues and cells for medical purposes. Article 14 of the Human Tissue Act declares that donors, their relatives or any other person authorized to represent the donor shall obtain all relevant information concerning the donation as it is set forth in the Human Tissue Donation Regulation. Additionally, Section (2) of the same Article also provides that the collection of tissues and cells from a living or deceased person, as well as the allocation and transplantation shall only be conducted in a manner and under the conditions laid down in the Transplantation Act.

While Articles 6-8 of the Human Tissue Donation Regulation provide

legal provisions on the consent of living donors to the donation of tissues and cells for medical and therapeutic purposes, Article 9 lays down rules on the donation of biological materials of deceased persons.

5.1. Consent of living donors

According to Article 6 of the Human Tissue Donation Act, living donors shall donate tissues and cells in the environment that secures their health, safety and privacy in the tissue and cell establishments and/or in donor centres licensed for tissue and cell procurement activity. Article 7 of the Regulation declares that prior to the donation, living donors shall confirm in writing that they have received, read and understood the conveyed information on the purpose and on the characteristics of the tissue and cell donation and procurement, on the donation related consequences and risks, on the envisaged investigations and personal data protection. The donors shall also declare that they voluntarily donate the tissues and cells and/or agree to the donation, that they have been informed about the opportunity to ask questions and shall receive satisfactory answers. The donors are also entitled to get the results of the analytical testing, including the explanation and have received the information on the safety and protection of personal data preventing from unauthorized disclosure of the identity of the donor of tissues and cells for autologous use, from disclosure of the details about his or her health and about the results of the testing completed on removed tissues and cells. In addition to the above, donors shall also confirm that they have re-

ceived the information on the possibility to withdraw and/or suspend themselves any time during the removal procedure, without any drawbacks.

The same article of the Regulation also lays down that donors and potential donors of tissues and cells for autologous use shall, in addition to the information mentioned above, receive the information on the therapy with tissues and cells for autologous use, such as prepared or approved by the person in charge on the part of the user and including the information as it is set out in the Regulation. The form of the statement about being familiar with and giving consent to the donation of tissues and cells for both allogeneic and autologous uses has been laid down in the Appendixes of the Regulation. Special provisions (Article 8) are applicable to the collection of haematopoietic stem cells from the umbilical cord blood of a live-born child and from the placenta; the purpose and the detailed specifications on the procurement of the above mentioned human tissues are laid down in Article 9 of the Transplantation Act and in other related regulations.

Additionally to the provisions of the Human Tissue Act's, Articles 7-11 of the Transplantation Act also provide detailed regulations on the removal of body parts from a living donor. According to Article 7 of the Transplantation Act, the removal of body parts from a living donor is subject to the donor's consent in writing and can only take place provided that the risk to his or her health is within acceptable limits according to medical criteria.

Article 8 also states that body parts may only be removed from a person older than 18 years of age, if he or she

is capable of making judgements. However removal of restorable tissues from a person under 18 years of age or from an adult who is not capable of making judgements is permissible, if reference is made to the transplantation of donated material into his or her brother or sister.

Nevertheless such medical intervention is subject to the consent of the Ethics Commission for Transplantations. The Transplantation Act also declares in Article 10 that the donor's consent shall refer to the planned intervention only. The consent shall be given in writing and shall be an expression of the donor's own free will developed on the basis of an appropriate explanation of the nature, the purpose and the course of the intervention, on the probability of the respective success as well as on the usual risks. Such explanation shall not be suggestive. The person involved shall be instructed about his or her rights and about the protection provided by the Act, in particular about the right to independent consultation concerning the risk to his or her health, provided by a doctor who is not involved in the removal or transplantation of the organ and is not a personal physician of the recipient.

The consent may only be given by an adult capable of making judgements and it is bound by the condition that the donated material be transplanted into a specified person. However the donor may withdraw his or her consent at any time before the beginning of the intervention.

The Transplantation Act also states that the legal representatives are those who have to give their informed consent in the case of minors and persons incapacitated, but if the latter are able

to understand the intervention they have to be considered even in case of opposition.

According to Article 11 of the Transplantation Act, the consent of a minor who has not acquired full legal capacity, or of an adult person whom a court ruling is entirely deprived of the capacity, shall be given by his or her legal representative. If the minor is already 15 years old and is capable of making judgements, his or her consent shall also be required for the removal of his or her body part. However, no removal of a body part is permissible if the donor opposes it. Despite the consent of the legal representative, the encroachment should not be performed if the donor expressly objects and is able to understand the meaning of his or her statement.

5.2. Provisions on deceased persons

Deceased donors, in line with Article 9 of the Human Tissue Donation Regulation, shall donate tissues and cells upon the acquisition of the consents and approvals in the manner and at the terms and conditions specified in the Transplantation Act and the Regulation.

Article 13 of the Transplantation Act sets forth that body parts may be removed from a deceased person for transplantation purposes on the condition that the donor has given his or her consent prior to his or her death and that the consent in writing has been produced as an official record. The consent shall be made in the presence of a person authorized by an authority or organization that has been empowered to engage into activities for the acquisition of donors' body parts for

transplantation purposes. Subject to the donor's consent, the consent in writing may also be officially registered on his or her health insurance card. In relation to the insurance card it is also worthwhile to mention that according to the report of the Council of Europe on biomedical research¹⁹:

"Transplantation medicine is well established in Slovenia, and public attitude towards organ donation after death is rather favourable. Electronic health and social security card²⁰, which is just being introduced, optionally contains the holder's statement about whether he or she wishes or does not wish to donate organs after death. This information is only accessible under special conditions in order to protect the holder from any possible misuse."²¹

Based on the consent in writing a body part may be removed from the donor after his or her death and after prior notification of the donor's closest relative.

However Article 14 also states that the removal of human body parts from a deceased person for transplantation purposes shall also be possible whenever the deceased person is the holder of a special donor card issued by Red Cross of Slovenia or by any other organization authorized by the Minister for the respective purpose. In addition to the above, the body part to be transplanted shall solely be removed from

the card holder on the condition that his or her closest relatives have been informed beforehand of the proposed removal and they do not explicitly oppose it.

The body parts of a deceased person who was a citizen of the Republic of Slovenia and/or had his or her permanent residence in the Republic of Slovenia may also be removed for transplantation purposes whenever the deceased person has neither explicitly given his or her consent to the transplantation nor explicitly prohibited it, unless it ensues from other circumstances that the deceased person would have opposed the removal. If the details on the deceased person's approach to donorship are contradictory, no removal can be carried out.

Notwithstanding the provision of the preceding provision, no removal of a deceased person's body parts shall be carried out if a person close to the deceased person opposes the removal. If such persons can be reached, it is necessary to inform one of them of the envisaged removal and of their right of refusal. Such person shall be given reasonable time for his or her decision.

The body parts of a deceased person who was not a citizen and/or a permanent resident of the Republic of Slovenia may be removed for transplanta-

¹⁹ Report for the Steering Committee on Bioethics (CDBI) of the Council of Europe on organ transplantation available in English at: http://www.coe.int/t/dg3/healthbioethic/source/Organ_Transplantation_en.doc.

²⁰ The health insurance card is an electronic personal document that needs to be presented at a doctor visit. The card is issued, free of charge, to every person upon the first regulation of the compulsory health insurance status. Validity of the card is updated by the card holders autonomously, through the self-service terminals, installed in hospitals or similar institutions.

<http://www.migrantservicecentres.org/userfile/Destination%20Country%20Fact%20Sheet%20SLOVENI.pdf> Further information is available at http://www.ehealthurope.net/news/4860/slovenia_rolls_out_e-health_card

²¹ For further information please consult: http://www.ehealthurope.net/news/4860/slovenia_rolls_out_e-health_card

tion purposes on the condition that the person close to the deceased gives his or her explicit consent.

The persons close to the deceased person are: spouse or non-married partner, adult children, parents, brothers and sisters as well as persons who were, judging from general circumstances, close to the deceased.

Due to the fact that personal data is also processed in relation to the donation and procurement of human tissues, Article 6 of the Personal Data Act is also relevant, according to which personal consent of an individual shall mean a voluntary statement of the will of an individual that his or her personal data may be processed for a specific purpose, and this is given on the basis of information that must be provided to such individual by the data controller pursuant to the Personal Data Act. Article 8 of the Act lays down that personal data may only be processed if provided by statute, or if the personal consent of the individual has been given for the processing of certain personal data.

The purpose of processing personal data must be provided by statute, and in cases of processing data on the basis of personal consent of the individual, the individual must be informed in advance in writing or in another appropriate manner of the purpose of processing personal data.

According to Article 6 of the Data Protection Act, the personal consent of an individual may be written, oral or may take some other appropriate form (Article 6 Point 14.).

The Personal Data Act further details the above mentioned rules and

sets out in Article 6 Point 15 that the written consent of the individual shall mean the signed consent having the form of a document, the provision of a contract, the provision of an order, an appendix to an application or other form in accordance with a statute. Additionally a signature shall also mean on the basis of a statute, a form equivalent to a signature given by means of telecommunication and a form equivalent by statute to a signature given by an individual who does not know how to write or is unable to write.

However, Article 6 Point 16 states that oral or other appropriate consent of the individual shall mean a consent given orally or by means of telecommunication or other appropriate means or in some other appropriate manner from which it can be concluded unambiguously that the individual has given his or her consent.

In addition to the above mentioned legislative measures, the Slovenian Patient Rights Act as a background, general legal act, also sets forth detailed provisions on the requirements and conditions of patients under medical treatment. Article 26 of the Patient Rights Act also declares that the patient has the right to independent decision-making about their treatment under the conditions provided by law.

According to the opinion of the NMEC on clinical research activities that involve the procurement and processing of genetic information²², since the collection and analysis of genetic information are considered to be situations where data protection

²² Available in English at <http://www.kme-nmec.si/Docu/Chapter24Slovenia.pdf>

rights may easily be violated, they suggest “to inform the proposers of molecular genetic studies that an approval is only granted for the particular study submitted, and that any new study on the same material is subject to a new review. The donors of the material must also be so informed. They must have a choice to give their consent only to the present study [...] and in case of any new study to be asked for a new consent. A request for blank advance consent for any future studies is in principle only acceptable for irreversibly anonymized material.”

It is also worthwhile to mention that before the adoption of special legislative measures on the procurement and collection of human tissues and cells, the opinion and general practice of the National Medical Ethics Committee was followed.

6. ACCESS TO DATA AND SAMPLES AND ANONYMITY

Article 11 of the Human Tissue Act sets forth the main regulation on the import and export along with input and output of tissues and cells. According to the relevant provisions of the Human Tissue Act, the import of tissues and cells from third countries and the respective export into third countries as well as their input from and output into other EU member countries shall be undertaken by tissue and cell establishments accredited and licensed for the respective activity. The imported and the input tissues and cells shall be traced from the donor to the recipient and vice versa in accordance with the proce-

dures prescribed by the Minister responsible for health issues. The tissue and cell establishments that import tissues and cells from third countries shall ensure that they meet the standards of quality and safety, such as laid down in the Human Tissue Act.

The Agency of Medical Products and Devices for the Slovenian Republic JAZMP, as a state entity responsible for the supervision of tissue and cell establishments shall take all necessary measures to ensure that all exports of tissues and cells to third countries are undertaken by tissue establishments accredited and licensed for such activity. Additionally all details on the import and export shall also be communicated to Slovenia-transplant. In emergency cases, the import or export of tissues and cells along with their input or output shall be approved by the Agency on the proposal of Slovenia-transplant.

Furthermore, the JAZMP shall also take all necessary measures to ensure that the imported or exported, input or output tissues and cells meet the quality and safety standards equivalent to those laid down in the Human Tissue Act.

The procedures for verifying the adequacy of quality and safety standards for the imported or exported biological materials shall be determined by the Minister of Health in the Human Tissue Import/Export Regulation.

According to the ‘Survey on opinions from National Ethics Committees or similar bodies, public debate and national legislation in relation to human biobanks’ conducted by the European Commission Research Di-

rectorate-General in 2004²³, a recommendation formulated by the Slovenian National Medical Ethics Committee sets forth fundamental requirements for the privacy and confidentiality of personal medical data in research projects where research is done on archived biological materials of human origin not collected prospectively for those particular studies.

In line with the recommendation “in the course of a research study, early anonymisation of the material is required and before the biological material (or information) is used for a research purpose not foreseen and approved at the time of its collection, consent of the data subject should be sought and obtained if reasonably possible. [W]hen this is not possible or the effort and cost would be disproportionate to the (minor or remote) possibility of damage to the interests of privacy and confidentiality, the ethics committee may absolve the researcher from the duty to seek consent. The patient may give a blanket consent to all future uses of his or her stored specimens, or may opt to be asked for consent to any new use, or may refuse consent to further storage after the study is completed. If a patient withdraws from a study, he or she may opt to have his or her biological samples removed and prohibit destroyed and further use of any identifiable personal information.”

7. STORAGE

With regard to the processing and storage of human tissues and cells, Article 10 of the Human Tissue Act sets forth the main requirements on the traceability of such biological materials.

According to the Human Tissue Act, the donor centre and the tissue and cell establishment shall take all necessary measures to ensure that all tissues and cells procured, processed, stored or distributed in the Republic of Slovenia can be traced from the donor to the recipient and vice versa. This traceability shall also apply to all relevant data relating to products and materials coming into contact with tissues and cells. In order to comply with the rules set forth in the Act, the donor centre and the tissue and cell establishment shall ensure the implementation of a donor identification system applicable to tissues and cells as well as to each of the products associated with such donation.

All tissues and cells must be identified with a label that contains the information determined by the Minister of Health in the Traceability Regulation. The donor centre, the tissue and cell establishment and the users of tissues and cells shall keep the data necessary to ensure traceability at all stages for a minimum of 30 years after clinical use. The data may also be stored in electronic form and shall be communicated to Slovenia-transplant running a central information system.

²³ Matthiessen, Line & Pitkänen, Kimmo (eds.) (2004): Survey on opinions from National Ethics Committees or similar bodies, public debate and national legislation in relation to human biobanks. European Commission Research Directorate-General, Directorate E, Biotechnology, Agriculture and Food, Update October 2004.

According to Article 15 of the Human Tissue Act donor centers and tissue and cell establishments shall secure that all data stored in such establishments, including genetic information, be under specific conditions accessible by third parties, that they remain anonymous to the extent that neither the donor nor the recipient can be identified.

In order to comply with the legal requirement of anonymisation and with reference to obligations under data protection legislation, donor centers and tissue and cell establishments shall ensure the compliance with the relevant provisions of the Personal Data Protection Act and they shall also ensure the adoption of all safeguards against unauthorized additions, deletions or modifications and transfer of information from donor files and/or deferral records. Additionally, such establishments shall also ensure the introduction of procedures to resolve data discrepancies and the avoidance of unauthorized disclosure of information, yet guaranteeing the traceability of donations.

The recipient and the donor of tissues and cells shall observe the principle of anonymous approach in the way that the donor or his or her family shall not be disclosed the identity of the recipient and vice-versa, except in case of donation from a living relative, such as regulated by the Transplantation Act.

Furthermore, the donor centre engaged in transplantation activity and guaranteeing traceability shall keep a donor database including the following data:

- Identification of the donor (name, surname, date of birth, residence, details on health insurance);
- Age, sex, health and family anamnesis along with information about habits, to

the extent sufficient for the application of the standards for refusal of the donor;

- Results of bodily examination;
- Clinical results, laboratory test results and results of other completed tests;
- Duly documented survey of an overall evaluation of the donor in accordance with the selection standards;
- Decision on or consent to donation;
- Details on the removed part of the human body;
- Details on the destination of the human body parts;
- Report on adverse events and reactions, including an analysis of the cause and effect;
- Other health related information as required.

Article 17 of the Human Tissue Act also provides that the tissue bank engaged in transplantation activity and guaranteeing traceability shall keep a database on the accepted, tested, preserved, processed, stored and distributed or otherwise removed tissues and cells, including the following data:

- Details on the source and destination of the tissues and cells intended for human therapeutic purposes;
- Details on the type of tissues and cells;
- Details on the tissue and cell handling procedures from their acceptance till their distribution;
- Duration of storage of tissues and cells;
- Storage conditions;
- Report on adverse events and reactions, including an analysis of the cause and effect;
- Permit, including the purpose for which the tissues and cells may be

- used (i.e. for therapeutic or research purposes or both), including all specific instructions for removal if the tissues and cells are not used for the purpose for which the approval was granted;
- All required records related to the procurement and information on the donor's history, such as conveyed by the donor centre;
- Results of physical, laboratory and other tests (e.g. an autopsy report);
- Duly documented survey of an overall evaluation of the donor in accordance with the selection standards imposed by an authorized and duly qualified person;
- In case of cell cultures intended for autologous use, documented hazard of allergic reactions to the recipient's medicinal products (e.g. antibiotics).

In line with Article 18 of the Human Tissue Act, the user of tissues and cells intended for carrying out the transplantation activity and for guaranteeing traceability shall keep a database of tissue and cell recipients, including the following data:

- Identification of the recipient (name, surname, date of birth, residence, details on health insurance);
- Age, sex, health and family anamnesis along with information about past behaviour, to the extent necessary for submitting the waiting list for the transplantation;
- Results of bodily examination;
- Clinical results, laboratory test results and results of other completed tests;
- Consent to the transplantation of tissues and cells;
- Details on the transplanted tissues and cells;
- Details on the recipient's health condition after the transplantation;

- Details on the destination of the transplantation of tissues and cells, such as submitted by the donor centre or tissue bank;
- Report on adverse events and reactions, including an analysis of the cause and effect.

The donor centre, the tissue bank and the user of tissues and cells shall promptly communicate all details on donors, recipients as well as on tissues and cells to Slovenia-transplant that – in order to provide for coordinated transplantation activity, keeping of waiting lists, allocation and exchange of tissues and cells, for control and statistical purposes –, keeps a central register of users of (1) tissues and cells and (2) personal details of donors and recipients of tissues and cells, including the data invoked in Articles 16 and 18 of the Human Tissue Act, and (3) tissues and cells, including the data as set out in the Human Tissue Act.

The personal details of donors and recipients, as well as data on tissues and cells shall be preserved for at least thirty years after the transplantation of tissues and cells.

In order to provide human body parts for therapeutic purposes, Slovenia-transplant shall also establish and run a database of potential donors and recipients of tissues and cells, including the following data:

- Identification of the recipient (name, surname, date of birth, residence, details on health insurance);
- Potential donor's decision on or consent to the donation;
- Potential recipient's consent to the transplantation;
- Details on the health condition of the potential donors and recipients, if

- required for the selection of the donor and of the recipient;
- Results of genetic screening with potential donors of haematopoietic stem cells.

Additionally to the Human Tissue Act and the Traceability Regulation, Article 4 of the Human Tissue Processing Regulation also provides detailed provisions on the storage and release of human tissues and cells.

8. SUPERVISION, PENALTIES

As it is mentioned above, the Agency for Medicinal Products and Medical Devices of the Republic of Slovenia, JAZMP²⁴ is the responsible state authority appointed to implement supervisory inspections and control measures with regard to the management of tissue and cell as well as activities of production, testing, processing, preservation, storage, allocation and distribution of tissues and cells intended for human use. The JAZMP was formed on 1 January 2007 by merger of the Agency for Medicinal Products and Medical Devices (Agencija za zdravila in medicinske pripomočke - ARSZMP), which operated under the Ministry of Health, and the National Institute for Pharmacy and Drug Research (Zavod za farmacijo in za preizkušanje zdravil - Ljubljana - ZAF). JAZMP as a new legal person assumes the rights and obligations of ARSZMP and ZAF. According to Article 37 of the Human Tissue Act the supervision of the implementation

of the Act shall be provided by the JAZMP. Furthermore Articles 6-7 of the Human Tissue Act set forth the tasks and obligations of the JAZMP in the respective legal domain²⁵.

In addition to the above, the competent authority in relation to transplantation activities is the Institute for Transplantation of Organs, Tissues and Cells of the Republic of Slovenia or Slovenija transplant.

According to the Human Tissue Act the JAZMP shall in the field of the quality and safety of human tissues and cells conduct procedures for the authorisation for collection, testing, preparation, processing, storage and/or distribution of blood and blood preparations, authorisations for obtaining, testing, processing, conserving, storing and/or distributing human tissues and cells, intended for treatment. Additionally, the JAZMP shall also perform its task in relation to procedures for the authorisation of importing/admission or exporting/removal of human tissues and cells on the proposal of Slovenija-transplant. In addition to the above, the Agency shall also collect reports from donor centres on severe adverse events and reactions, and report on the analyses of causes and effects, related to obtaining, testing, processing, storing, allocating and distributing tissues and cells, as well as the observing any adverse reactions during or after clinical use, which could be related to the quality and safety of tissues and cells and it also reports to the European Commission at its request on activities undertaken in the field of histovigilance²⁶.

²⁴ <http://www.jazmp.si>

²⁵ See also part 3. on the establishment and management of biobanks.

²⁶ <http://www.jazmp.si/index.php?id=105>

8.1. Ethical Committees

At the national level the National Medical Ethics Committee (NMEC) is the only research ethics committee, the members of which are appointed by the Minister of Health for a four-year term²⁷. The tasks and duties of the National Medical Ethics Committee are governed by Act 30 of 1995 on the Regulations governing the composition, duties, responsibilities, and operation of medical ethics²⁸.

Local ethics committees have recently been set up at university and regional hospitals. The NMEC reviews all biomedical research funded by the State agencies or institutions, all multi-centre and multinational clinical trials, all biomedical research on humans conducted in the framework of M.Sc. or D.Sc. theses, as well as all research on humans raising important ethical questions. Such projects submitted to local committees must be referred to the NMEC. The local or regional ethics committees are only authorised to review local studies that do not present any serious risk to the , such as for example non-invasive and observational research. The NMEC also gives opinions on bioethical issues, advises the parliament and assists in formulating relevant laws. It has also produced

guidelines for researchers carrying out research involving humans. There is no possibility of appeal against the decision of NMEC²⁹.

According to the Patient Rights Act, the Ministry of Health is obliged to monitor the implementation of the Act. The respective authority, the Health Inspectorate of the Republic of Slovenia is vested with the power to exercise the rights of the Ministry under the Act³⁰.

The Patient Rights Act also lays down the competencies of the Human Rights Ombudsman in the area of patient rights. According to Article 55 of the Patient Rights Act, the ombudsman is obliged to monitor the enforcement of patient rights. In line with the conducted monitoring in the relevant field, the ombudsman can request that the responsible national bodies, local community bodies and holders of public powers enable the conditions for effective enforcement of the Act. The ombudsman appoints one of his or her representatives to act in the field³¹.

8.2. Penalties

Article 39 of the Human Tissue Act sets forth the penalties imposed on those who failed to comply with the Act; a fine between EUR 500 and EUR

²⁷ The Statutory Notes (SN) of the NMEC is available at: <http://www.mf.uni-lj.si/kme-nmec>

²⁸ Pravilnik o sestavi, nalogah, pristojnostih in načinu dela komisije za medicinsko etiko, Ur.l. RS, št. 30/1995, Ur.l. RS, št. 69/2009. Available in Slovenian at: <http://www.uradni-list.si/1/objava.jsp?urlid=199530&stevilka=1474> In English: Regulations governing the composition, duties, responsibilities, and operation of medical ethics, Official Gazette, 30/1995, 69/2009.

²⁹ Jozef TRONTELJ, Research Ethics Committees in Slovenia. In: Research Ethics Committees, Data Protection and Medical Research in European Countries: PRIVIREAL, ed. D. Beylvelevd, D. Townend and J. Wright, University of Sheffield, UK. August 2005. Available in English at: <http://www.kme-nmec.si/Docu/Chapter24Slovenia.pdf>.

³⁰ Zdravstveni inšpektorat RS (ZIRS) (Health Inspectorate of the Republic of Slovenia) <http://www.zi.gov.si/en/>

³¹ <http://www.varuh-rs.si/pravni-okvir-in-pristojnosti/ustava-zakoni/zakon-o-pacientovih-pravicah/?L=6>

100,000 shall be imposed on a legal person if the tissue and cell establishment performs its activity without being licenced by the JAZMP; if the tissue and cell establishment keeps the documents and the records contrary to the provisions of the Act; if tissues or cells are distributed or applied without any traceability evidence or tissues and cells are imported or exported without any traceability evidence on the way from the donor to the recipient and vice versa or if tissue; or cells are imported or exported without any licence. The same sanction is applicable in cases when the tissue and cell establishment fails to provide for the donor's personal data protection and confidentiality or if

donor centres and tissue and cell establishments fail to secure the anonymity of all personal data under the Human Tissue Act.

Additionally the same legal consequences shall prevail in case the recipient receives tissues and cells without any confirmation in writing of being informed and without his or her consent or if tissues and cells are received by a minor under fifteen years of age without his or her parents' consent and/or by an adult deprived of his or her business capacity by court decision without his or her representative's consent. Furthermore, the responsible person of a legal entity shall be fined between EUR 40 and EUR 4,000 for the previously mentioned offences.

II. FORENSIC BIOBANKS

1. RELEVANT LAWS

There is no specific law on forensic databanks in Slovenia. However according to the current practice the Slovenian Police Force is entitled to collect any information of an evidential nature in the interest of criminal investigation. The Police in line with the provisions of the Police Act³² is also entitled to manage the Slovenian forensic database, operated and managed within the Ministry of Interior, General Police Department, within the Forensic Science Laboratory³³.

The relevant provisions of the Data Protection Act are also applicable to forensic databases and the collection of genetic information for investigat-

ing purposes. Apart of the above mentioned provisions set forth in the Data Protection Act, the Criminal Code³⁴ and Criminal Procedural Code³⁵ are also worth mentioning. In relation to the Police Act, the Rules on the protection of police data³⁶ also have to be noted.

2. MANAGEMENT AND SUPERVISION

As it is mentioned above the Slovenian Police Force is entitled to manage the forensic database. The database including approximately 17.000 profiles was established 10 years ago. The forensic database is an independent unit within the General Police Directorate. In the DNA da-

³² Zakon o policiji (uradno prečiščeno besedilo) (Zpol-UPB4) Ur.l. RS, št. 70/2005. Available in Slovenian at: <http://www.uradni-list.si/1/objava.jsp?urlid=200570&stevilka=3112> In English: Police Act, Official Gazette, 70/2005.

³³ Center za forenzične preiskave or CFP (Forensic Science Laboratory) <http://www.enfsi.eu/page.php?uid=144>

³⁴ Kazenski zakonik Republike Slovenije (KZ) Ur.l. RS, št. 63/1994 (70/1994 popr.), Ur.l. RS, št. 23/1999, 60/1999 Odl.US: U-I-226/95, 40/2004, 95/2004-UPB1, 37/2005 Odl.US: U-I-335/02-20, 17/2006 Odl.US: U-I-192/04-16, 55/2008 (66/2008 popr.), 89/2008 Odl.US: U-I-25/07-43, 5/2009 Odl.US: U-I-88/07-17. Available in Slovenian at: <http://www.uradni-list.si/1/objava.jsp?urlid=199463&stevilka=2167> In English: Criminal Code, Official Gazette, Nos. 63/94, 70/94 – correction, 23/99, 40/2004 and 95/2004, 95/2004-UPB1, 37/2005 Odl.US: U-I-335/02-20, 17/2006 Odl.US: U-I-192/04-16, 55/2008 (66/2008 popr.), 89/2008 Odl.US: U-I-25/07-43, 5/2009 Odl.US: U-I-88/07-17. Non-official English translation from 7 of September 2007 is available at www.policija.si/portal_en/zakonodaja/pdf/PenalCode2007.pdf

³⁵ Zakon o kazenskem postopku (ZKP-UPB4), Uradni list RS, št. 32/2007 z dne 10. 4. 2007, Available in Slovenian at: <http://www.uradni-list.si/1/objava.jsp?urlid=200732&stevilka=1700> In English: Criminal Procedural Code, available at:

http://www.policija.si/portal_en/zakonodaja/pdf/CriminalProcedureAct2007.pdf

³⁶ O varovanju podatkov policije, Uradni list RS, št. 79/1999 z dne 30. 9. Available in Slovenian at: <http://www.uradni-list.si/1/objava.jsp?urlid=199979&stevilka=3762> In English: Rules on the protection of police data, Official Gazette. 79/1999 dated 30. 9. 1999

tabank the profiles are kept, whereas amples are physically destroyed once profiles had been derived³⁷.

According to Article 58 of the Police Act, the collection, processing, storing, forwarding and use of data from police records shall be subject to the provisions of the Personal Data Protection Act which is in compliance with 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, which again in Article 3 Section (2) grants an exception to "operations concerning public security, defence, State security (including the economic well-being of the State when the processing operation relates to State security matters) and the activities of the State in areas of criminal law."

3. SAMPLES AND SAMPLE TAKING, CONSENT

According to Article 148 of the Criminal Procedural Act, if grounds exist for suspicion that a criminal offence to be prosecuted *ex officio* has been committed, the police shall be bound to take steps necessary for finding the perpetrator. The Police is obliged to ensure that the perpetrator or his or her accomplice does not go into hiding or flees, furthermore they are obliged to detect and preserve traces of crime or objects of value as evidence, and collect all information that may be useful for the successful conducting of crimi-

nal proceedings. The police in order to ensure its duties under the Criminal Procedural Code, is entitled to take a photograph of the person suspected of a criminal offence as well as his or her fingerprints and an oral mucous membrane swab. They may also publish his or her photograph if that is necessary for establishing his or her identity and if it is important for the successful conducting of criminal proceedings. Furthermore where it is necessary to ascertain the identity of fingerprints and biological traces on individual objects, the police may take fingerprints and mouth swabs of persons. (Article 149).

In line with Article 266 of the Criminal Procedural Act physical examination of the accused persons in criminal investigation shall be performed even without their consent when it is necessary to establish facts material to criminal procedure. Physical examination of other persons may be performed without their consent only when it is necessary to establish if a particular trace or consequence of criminal offence has been left on their body.

Furthermore taking of blood samples and other medical procedures normally undertaken for the analysis and determination of other facts of importance for criminal procedure may be performed without the consent of the person being examined, save where such procedures would be harmful to his or her health. The application of such medical interventions on the accused persons or witnesses, just like the application of agents that would influence their will when giving testimony shall be prohibited.

³⁷ Interview conducted at the Slovenian forensic biobank with Katja Drobnič and Aleksander Regent on 19 January 2008.

4. PURPOSE AND SCOPE OF COLLECTION

According to Article 59 of the Police Act the police shall administer personal data collections and the data shall be collected, processed, stored, forwarded and used by police officers.

In the exercise of police powers, the police keep and maintain the records of DNA tests as well as several other records (record of identification, record of persons sought by the police, record of detained and retained persons, record of fingerprinted persons etc.) as set forth in Article 59 Section (2). In line with the same provision of the Police Act, the Minister of Interior shall prescribe in detail the method of keeping police records.

Furthermore Article 60 of the Police Act declares that the above mentioned records shall contain the following personal data: name and surname; birth data (day, month, year and place of birth); personal registration number; sex; address of permanent or temporary residence; nationality.

In addition to the personal data mentioned previously, Article 61 of the Police Act sets forth types of information that the criminal records shall contain.

- The record of criminal offences shall contain: nickname or false name, description of personal identifiers, nationality of the reported person or the suspect, the administrative unit of his or her place of birth, family background and financial situation, educational background, profession and employment, personal data of the victims, reporting persons or other persons who gave information on the criminal offence, and informa-

tion on the criminal offence (type, place, time, modus operandi, motive, description of items involved in the commission of the offence, damage and other circumstances of commission);

- Record of perpetrators shall contain: perpetrator's profession and employment, the post he or she holds (if he or she is an accountable person of a legal entity), personal information on the victim and information on the misdemeanour (type, place, time, method of operation, motive, participants and damage);
- Record of persons sought by the police shall contain: nickname or false name of the person sought by the police, photograph and description of personal identifiers, family background and financial situation, educational background, profession and employment;
- Record of identifications shall contain: grounds, place, time and means of transportation of the person whose identity was established, and other circumstances of establishing the person's identity;
- Record of persons against whom covert investigation measures set forth in the act governing the criminal procedure have been taken shall contain: nickname or false name of the person, family background and financial situation, educational background, profession and employment, number of the written order issued by the state prosecutor or investigating judge, and information on the method, extent and duration of the measures taken;
- Record of DNA tests shall contain: place, time and grounds for taking a DNA sample, name and surname of

the person who took the sample, profile of the DNA sample taken;

Article 105 of the Criminal Code also sets out that a criminal record shall contain (1) the personal data on perpetrators of criminal offences; (2) information on the imposed punishments, security measures, convictions by probation, court admonitions and the remitted punishments referring to the perpetrators of whom a record is being kept; as well as (3) the legal consequences incident to them; (4) later alterations of data on convictions that were entered in the criminal record; as well as (5) data on the enforced punishments and (6) on the annulment of the entry of unjustified conviction.

Furthermore the same Article also sets forth that a special record shall be kept with respect to educational measures. It shall contain personal data on a juvenile, data on the educational measures imposed and enforced, as well as all other data relating to the enforcement of educational measures.

In addition to the above mentioned provisions of the Police Act, the Criminal Code of the Slovenian Republic also sets out relevant provisions on the storage and processing of criminal records.

With reference to the statutory rehabilitation and deletion of conviction, Article 103 of the Criminal Code declares that by means of statutory rehabilitation, the conviction shall be deleted from the criminal record, the legal consequences of the conviction shall cease to apply and the convicted person shall be deemed never to have been convicted.

The conviction shall be deleted from the criminal record within the pre-

scribed period of time from the day the punishment was enforced, barred by the statute or remitted, unless in such a period the convicted person commits another criminal offence. The above mentioned time period shall be (1) one year from the court decision that convicted the perpetrator or remitted his or her sentence; (2) one year from the expiry of the term of suspension in case of probation; (3) three years, for conviction to a fine, accessory sentence, or to imprisonment no more than one year or to juvenile imprisonment; (4) five years for a conviction to imprisonment between one and three years and (5) eight years, for a conviction to imprisonment between three and five years. Furthermore, such time period shall be (6) ten years, for a conviction to imprisonment of five to ten years and (7) fifteen years, for conviction to imprisonment of ten to fifteen years. However conviction to punishment by imprisonment above fifteen years shall not be deleted from the criminal record. According to Article 103 Section (6) “[A] conviction may not be deleted as long as security measures apply [to the perpetrator]”.

Article 104 of the Criminal Code provides rules on the court rehabilitation of convicted persons. According to the aforementioned provision of the Criminal Code “[U]pon a request from the convicted person, the court may order the deletion of the conviction from the criminal record and that the convicted person be deemed never to have been convicted, provided that half of the statutorily prescribed period has elapsed by expiry of which the conviction is removed [from the criminal conviction records], and with the further proviso that during this period the con-

victed person has not committed another criminal offence. When deciding on whether to delete the conviction, the court shall consider the convicted person's behaviour after he or she has served his or her punishment and the nature of the criminal offence [he or she committed], as well as other circumstances relevant to the deletion of the conviction."

Data from the criminal record may be released only with respect to convictions that have not been deleted. According to Article 105 Section (3) recipients might be the court, the state prosecutor's office and bodies of the law enforcement dealing with criminal proceedings against a previously convicted person, bodies responsible for the enforcement of penal sanctions and bodies involved in the procedures for granting an amnesty, pardon or for overwriting a conviction. Data on a conviction which was not deleted may be released to the state bodies, legal persons and private employers upon a reasoned request only if the legal consequences of the conviction or of the security measures are still in effect or if such persons show a legitimate and legally-grounded interest (Article 105 Section (4)). Upon his or her request, an individual may be provided with data on whether he or she was convicted and not only when he or she needs them for the assertion of his or her rights.

5. ACCESS TO DATA AND SAMPLES

According to Article 62 of the Police Act an individual has the right to access the data relating to himself or

herself which is contained in the records of persons sought by the police, record of identifications and the record of DNA tests, as well as further records as set forth in the Act.

An individual whose personal data has been collected without his or her knowledge and has not been deleted shall be notified of this when the nature of policing allows so.

In line with Article 36 of the Personal Data Protection Act the rights of an individual set out in Article 19 (right to information on the data processing), Articles 30 (right of the individual to information) and 32 (right to supplement, correct, block, erase personal data) of the Act may exceptionally be restricted by statute for reasons of protection of national sovereignty and national defence, protection of national security and the constitutional order of the state, security, political and economic interests of the state, the exercise of the responsibilities of the police, the prevention, discovery, detection, proving and prosecution of criminal offences and minor offences, the discovery and punishment of violations of ethical norms for certain professions, for monetary, budgetary or tax reasons, supervision of the police, and protection of the individual to whom the personal data relate, or the rights and freedoms of others.

Article 85 of the Personal Data Protection Act also sets forth that connecting filing systems from criminal record and minor offence records with other filing systems, and connecting filing systems from criminal records and minor offence records, shall be prohibited.

According to Article 54 Section (3) and Article 59 of the Police Act, fur-

thermore according to Article 12 of the Act on State Attorneys³⁸ and Article 160b of the Criminal Procedural Code police officers and prosecutors may have access to data. The latter provision of the Criminal Procedural Code also allows for a possibility that a foreign police officer, acting within Joint Investigation Teams by virtue of Council Framework Decision on Joint Investigation Teams (JITs)³⁹ can have access to databanks (including forensic biobanks) run by the Slovenian Police; and in other cases not falling under the jurisdiction of JITs the Police may grant access to personal data upon request and upon the condition of reciprocity. Slovenia is in a daily exchange of information with especially Austria, Germany, Netherlands, Spain and Luxembourg⁴⁰.

It is also worth mentioning that the Slovenian Police also makes use of and has access to Interpol's DNA database through the International DNA Gateway portal. In addition to the above Slovenia as a Member State of the European Union, takes part in the DNA data exchange and matching system used by the EU member states⁴¹ in line with Council Decisions 2008/615/JHA on the stepping up of cross-border cooperation, particularly in combating terrorism and cross-border crime and 2008/616/JHA on the implementation thereof⁴².

6. STORAGE

The Rules on the protection of police data establish the organisational and technical logic procedures and measures for the protection of personal and confidential data administered by the police. The measures and procedures set out in these rules are applied within the police to ensure the secure handling of personal and confidential data and to enable the continuous identification of when specific personal and confidential data were dealt with and who dealt with them, for the period for which the specific data are stored.

According to Article 3 of the Police Data Act, protected data may be handled only by a police employee who has been security vetted prior to the conclusion of an employment contract or transfer to a position where he or she is handling protected data. Article 2 of the Police Data Act sets forth that protected data shall mean personal or confidential data the handling of which must be accompanied by the implementation of specific security measures and procedures.

Article 63 of the Criminal Procedure Act sets out the time and period until when the relevant data in the criminal records shall be kept. According to this the records of DNA tests shall be kept until the police

³⁸ In original: Zakon o državnem pravobranilstvu (ZDPra-UPB2) št. 94/2007 z dne 16. 10. 2007, In original available at: <http://www.uradni-list.si/1/objava.jsp?urlid=200794&stevilka=4689>

³⁹ Council Framework Decision of 13 June 2002 on joint investigation teams.

⁴⁰ Interview conducted at the Slovenian forensic biobank with Katja Drobnic and Aleksander Regent on 19 January, 2008.

⁴¹ Further details on the DNA exchange of the Member States of the European Union available at DNA-database management review and recommendations of ENFSI DNA Working Group, April 2009. Available at: http://www.enfsi.eu/get_doc.php?uid=345.

⁴² <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2008:210:0012:0072:EN:PDF>

investigation procedure or protection activity has closed, or after a final ruling to initiate criminal or misdemeanour proceedings has been issued; if proceedings are not initiated, after prosecution becomes statute-barred. The statute of limitation in the latter cases can be found in Article 111 of the Criminal Code.

The state prosecutor's office that receives the crime report from the police shall be obliged to submit the decision on the final initiation of criminal proceedings to the competent police unit, on the basis of which the police shall set the deadlines for storage of information in the record of criminal offences.

Article 64 also sets forth that after the deadlines mentioned in Article 63 have expired, the data from the police records shall be handled in accordance with the regulations governing the operation of public administration bodies involving the permanent collection of documentary material or the handling of public archive material. Police officers and competent persons from other state bodies shall only be allowed to access to data in the course of an investigation based on a suspicion that a criminal offence for which the perpetrator is prosecuted *ex officio* has been committed, or in other cases determined by the law.

As to cross-linking, Article 20 of the Personal Data Protection Act may be relevant, which provides in Section (1) that whenever acquiring personal data from filing systems in the areas of health, police, national intelligence-

security activities, national defense, judiciary and the state prosecution and criminal record and minor offence records, the same connecting code may never be used in a manner that only such code would be used to obtain personal data, with the exception provided for in Section (2) that this is the only item of data in a specific case that can enable the detection or prosecution of a criminal offence that is to be persecuted *ex officio*, to protect the life or body of an individual, or to ensure the implementation of the tasks of the intelligence and security bodies provided by statute. In such cases an official annotation or other written record must be made thereof without delay.

7. SUPERVISION, PENALTIES

As it is mentioned above the relevant provisions of the Data Protection Act are also applicable to forensic databases. Furthermore the Office of the Information Commissioner⁴³ responsible for supervision of the implementation of the Personal Data Protection Act is entitled to supervise the management of the Slovenian Forensic Database. [Data Protection Act Article 11 Section (2)]

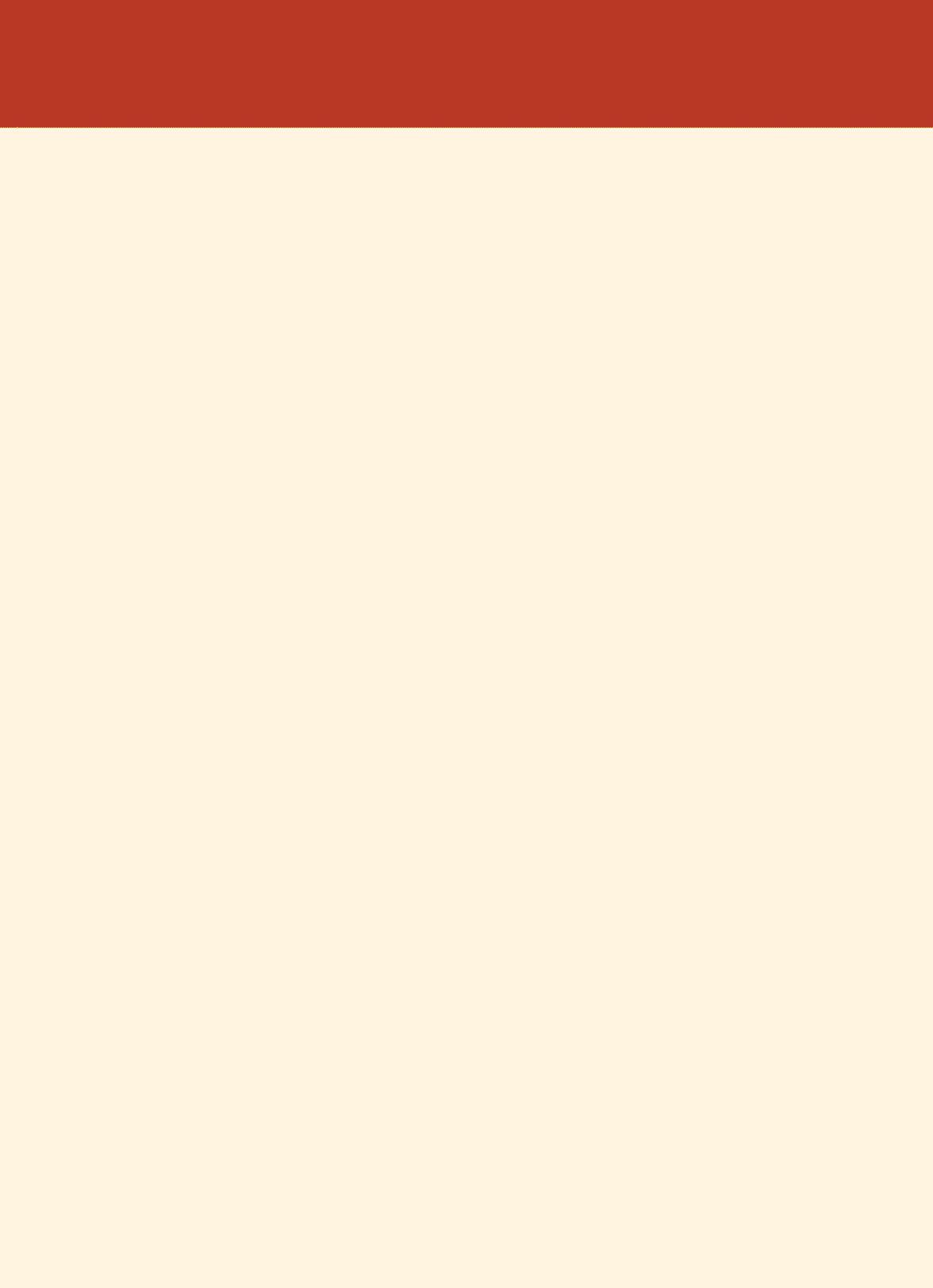
In line with Article 2b of the Police Act, the supervision of the police shall be carried out by employees of the Ministry who have police powers to do so. Their rights and obligations shall be equal to those of police officers. In addition to the above Article

⁴³ Informacijski Pooblaščenec (Information Commissioner of the Republic of Slovenia) <http://www.ip-rs.si/?id=195>

57 also sets out that the Minister of Interior shall determine the organisational, logistical and technical procedures and measures to be taken in order to protect personal and classified police information, as well as the criteria and procedures for defining the level of secrecy of data administered by the police.

According to Article 102 of the Personal Data Act, a fine between

EUR 830 and EUR 2.080 shall be imposed for a minor offence on the responsible person of a state body or body of self-governing local community, which connects filing systems from criminal record and minor offence records with other filing systems, or connects filing systems from criminal records with filing systems from records on minor offences.





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