

Open Research Repository

The legal regulation of biobanks: National report: Czech Republic

Item Type	Working paper
Authors	Sándor, Judit;Bárd, Petra
Publisher	Center for Ethics and Law in Biomedicine
Download date	2024-12-12 22:57:12
Link to Item	http://hdl.handle.net/20.500.14018/7267

No.11

CELAB PAPER SERIES

| C | E | L | A | B |



JUDIT SÁNDOR

PETRA BÁRD

THE LEGAL REGULATION
OF BIOBANKS

National Report:
**Czech
Republic**



CENTER FOR ETHICS AND LAW
IN BIOMEDICINE





Editors: Judit Sándor and Petra Bárd

© September 2009

Center for Ethics and Law in Biomedicine (CELAB)

ISSN 2074-4498

ISBN 978-963-88538-1-3

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 AduPrint Kft.

The present publication has been supported by GeneBanC, a Specific Targeted Research Project (STREP) funded by the European Commission in the Sixth Framework Programme. Contract number: FP6-036-751



TABLE OF CONTENTS

I. CLASSICAL AND POPULATION BIOBANKS	3
1. Relevant laws	3
2. Establishment and management of biobanks	4
3. Pecuniary aspects	6
4. Consent of people with full and limited legal capacity, provisions on deceased persons	6
5. Access to data and samples and anonymity	10
6. Storage	12
7. Supervision, compensation, penalties	15
8. Public debate	20
II. FORENSIC BIOBANKS	21
1. Relevant laws	21
2. Management	22
3. Samples and sample taking, consent	22
4. Purpose and scope of collection	23
5. Access to data and samples	23
6. Storage	24

THE REGULATORY FRAMEWORK OF THE ESTABLISHMENT, MANAGEMENT AND FUNCTIONING OF BIOBANKS IN THE CZECH REPUBLIC

As partners in the European Union Framework Project entitled “GeneBanC: Genetic bio and dataBanking: Confidentiality and protection of data” we are exploring the legal regulations of databanks. (<http://www.genebanc.eu/>) The Center for Ethics and Law in Biomedicine established at the Central European University, Budapest (<http://www.ceu.hu/celab>) aimed to investigate the existing regulatory framework of biobanks across the EU and focus on the collection and analysis of legislation and regulation regarding the establishment, management and functioning of classical, population and forensic biobanks across Europe. An important objective was to look at the similarities and differences in such legislation and regulations, in order to formulate recommendations towards a harmonization of European practices and regulations. The European jurisdiction was divided up into two parts between CELAB and the Belgian project partner, the Centre for Biomedical Ethics and Law, K.U.Leuven. CELAB was focusing on the regulatory framework of Cyprus, the Czech Republic, Estonia, Greece, Hungary, Italy, Latvia, Lithuania, Malta, Poland, Romania, the Slovak Republic, and Slovenia. The present booklet is the first one in the series of country reports prepared by CELAB.

In the framework of the research we have conducted several interviews with Hungarian experts and visited national biobanks. We are especially grateful to Josef Kuře, Professor at the University Centre for Bioethics and Department of Medical Ethics, Masaryk University, Brno and Lukáš Prudil associate professor at the Department of Social Medicine and Health Care Administration, Medical Faculty, Masaryk University, Brno.

The present paper summarizes the regulatory framework of biobanks in the Czech Republic 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 the regulatory background of forensic biobanks invoking legal issues of different nature will be covered separately in Part II. The present analysis does not address either the international standards, or European Union pieces of legislation, but it should be borne in mind that these are binding on the Czech Republic being a European Union Member State.

Budapest, 1 September 2009

I. CLASSICAL AND POPULATION BIOBANKS

1. 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, despite the fact that extensive human subject research is conducted in the Czech Republic. Although there is no comprehensive document, a number of general pieces of national legislation and international instruments are governing the field. The Oviedo Convention has become part of Czech law by being incorporated into Act No. 96/2001 Coll.,¹ which is the collection of international treaties. Other relevant laws include Act 20/1966 on Health Care, as amended;² Act No. 285/2002 Coll. on Transplantation, as amended (Transplantation Act);³ Act No. 101/2000 Coll.

of 4 April 2001 on Personal Data Protection,⁴ as amended,⁵ which is almost word by word implementing the EU Directive 95/46/EC on the protection of individuals with regard to the processing of personal data and on the free movement of such data (Data Protection Directive); Act No. 227/2006 Coll. on Research on Human Embryonic Stem Cells as amended;⁶ Act No. 296/2008 Coll. on Safeguarding the Quality and Safety of Human Tissues and Cells Intended for Human Use (Human Tissue and Cells Act)⁷ 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. The latter law is primarily a technical norm on quality as-

¹ In original language: 96/2001 Sdělení Ministerstva zahraničních věcí o přijetí Úmluvy na ochranu lidských práv a důstojnosti lidské bytosti v souvislosti s aplikací biologie a medicíny: Úmluva o lidských právech a biomedicině.

² In original language: 20/1966 Zákon o péči o zdraví lidu.

³ In original language: Zák. č. 285/2002 Sb. o darování, odběrech a transplantacích tkání a orgánů a o změně některých zákonů.

⁴ In original language: 101/2000 Zákon o ochraně osobních údajů a o změně některých zákonů. In English available at: <http://www.uouu.cz/uoou.aspx?menu=4&submenu=5>

⁵ The Act has been amended by Acts Nos. 227/2000, 177/2001, 450/2001, 107/2002, 310/2002, 517/2002, 439/2004, 480/2004, 626/2004, 413/2005, 444/2005, 109/2006, 112/2006, 342/2006, 170/2007 and 52/2009.

⁶ In original language: 227/2006 Zákon o výzkumu na lidských embryonálních kmenových buňkách a jeho prováděcí předpis. Available in English language at: <http://aplikace.msmt.cz/PDF/JJHumanstemcells.pdf>.

⁷ In original language: 296/2008 Zákon o lidských tkáních a buňkách.

insurance, storage, traceability and according to leading scholars in the field, should much rather take the form of a ministerial decree.⁸ Other pieces of background legislation are Act No. 79/1997 Coll. on the Collection of Pharmaceuticals and the amendments of related acts,⁹ and Act No. 123/2000 Coll. on the Collection of Laws of Medical Devices and related implementing regulations.¹⁰

Act 101/2000 of 4 April 2001 on Personal Data Protection (Data Protection Act) is heavily relied upon in the lack of a comprehensive specialized piece of legislation. The Act of 2000 still in force is based on the Data Protection Directive and on the Council of Europe Convention of 1981 for the Protection of Individuals with regard to Automatic Processing of Personal Data. The Data Protection Act in force replaced Act No. 256/1992 Coll. against which the main criticism was that it did not comply with the Data Protection Directive, and most importantly with its Article 28, the provision on a superviso-

ry authority.¹¹ By now the Personal Data Protection Office¹² has been established. In addition to the above the Penal Code No. 140/1961 Coll.¹³ also deemed relevant to the respective legal domain since the Code includes provisions prohibiting the unauthorized use of tissues or organs. Furthermore in relation to the establishment of bioethics committee under Act No. 227/2006 Coll. for the supervision of researches on human embryonic stem cells Act No. 130/2002 Coll. on Research and Development Support from Public Funds and on Amendment to Some Related Acts (Research and Development Support Act)¹⁴ also prove to be important.

2. ESTABLISHMENT AND MANAGEMENT OF BIOBANKS

In general there seems to be a missing conceptual approach and an unreasonable division of competencies among state bodies.¹⁵

⁸ Presentation of Lukáš Prudil at the Second International Workshop of the Tiss.EU project on Anonymisation and Pseudonymisation as a Means of Privacy Protection organized by CELAB, Budapest, 6-8 April 2009.

⁹ In original language: 79/1997 Zákon o léčivech a o změnách a doplnění některých souvisejících zákonů

¹⁰ 123/2000 Zákon o zdravotnických prostředcích a o změně některých souvisejících zákonů

¹¹ Martina Kocourková and Lukáš Prudil, Implementation of Directive 95/46/EC in the Domestic Law of the Czech Republic, In Deryck Beylveled, David Townend, Ségolène Rouillé-Mirza and Jessica Wright (eds.), Implementation of the Data Protection Directive in Relation to Medical Research in Europe, Aldershot: Ashgate, 2004, 47.

¹² In original language: Úrad pro ochranu osobních údajů, for further details please visit www.uouu.cz

¹³ In original language: Úplné Znění - Zákona c. 140/1961 Sb., trestní zákon jak vyplývá ze zmen a doplneni provedených zákony c. 120/1962 Sb., c. 53/1963 Sb., c. 56/1965 Sb., c. 81/1966 Sb., c. 148/1969 Sb., c. 45/1973 Sb., c. 43/1980 Sb., c. 159/1989 Sb., c. 47/1990 Sb., c. 175/1990 Sb., c. 457/1990 Sb., c. 545/1990 Sb., c. 490/1991 Sb., c. 557/1991 Sb., nálezem Ústavního soudu CSFR v částce 93/1992 Sb., zákony c. 290/1993 Sb., c. 38/1994 Sb. (úplné znění vyhlášeno pod c. 65/1994 Sb.), nálezem Ústavního soudu CR c. 91/1994 Sb. a zákonem c. 152/1995 Sb.

¹⁴ In original language: Úplnéznění zákona č.130/2002Sb.,opodpořevýzkumuavývojevěřejnýchprostředků aozměně některýchsouvisejících zákonů (zákonopodpořevýzkumuavývoje),jakvyplývávpozdějšíchzměn

¹⁵ Interview with and presentation by Lukáš Prudil at the Second International Workshop of the Tiss.EU project on Anonymisation and Pseudonymisation as a Means of Privacy Protection organized by CELAB, Budapest, 6-8 April 2009.

The creation of databases is not regulated by specific laws, therefore primarily the Personal Data Protection Act's provisions and a "technical norm" aimed at quality assurance, storage, traceability etc. of human tissues and cells, the so-called Act 296/ 2008 on Human Tissues and Cells are applied.

Article 2 of the Data Protection Act establishes the Office for Personal Data with its seat in Prague. In line with Article 16 Section (1) whoever intends to process personal data as a controller or alter the registered processing has to notify in writing the Office of this fact prior to commencing personal data processing. Section (2) enumerates the necessary elements of the notification. According to Article 16 Section (2) the notification to the Office for Personal Data Protection has to include the identification data of the controller (in case of a natural person who is not an entrepreneur: first name, surname, date of birth and address of permanent residence; in case of other persons their name, seat and identification number, and name of persons that are their statutory representatives); the purpose or purposes of processing; the categories of data subjects and of personal data pertaining to these subjects; the sources of personal data; description of the manner of personal data processing; the location or locations of personal data processing; the recipient or category of recipients; the anticipated personal data transfers to other countries; the description of measures adopted for ensuring the protection of personal data according to Article 13 on the obligations of persons in securing personal data discussed *infra* in Point 7.

Should all these data be included into the notification, data processing can start in 30 days from submitting the document. In all other cases, the Office informs the prospective data controller about the information that are missing

According to Article 29 Section (1) Point b. the Office is obliged to keep a register of personal data processing, which has to be made public in a manner enabling remote access, with all the above information, except for the description of the manner of data processing and the description of the adopted data protection measures. The public register of personal data processing is available on the web site of the Office in a form that enables search based on name, registration number or the company identification number.

In addition to the above Article 17 of Human Tissues and Cells Act provides legal regulation on the procedure for requesting permission for the operation of a tissue establishment. According to Article 17, Section (1) the application for obtaining a licence shall contain documents that appropriately certify the applicable medical facility and the qualification of legal or natural persons who perform their duty at the laboratory. The application shall also contain proof of the right to use the facilities and equipments for activities that are subject to the application which shall also contain appropriate data and documentation proving the eligibility of the applicant's obligations under the Act. The submitted application shall also specify the types of tissues and cells which are intended to be procured at the tissue establishment along with the other documents

certifying compliance with the qualification requirements imposed on the responsible person in accordance with Article 6 Section (2) and Article 8 Section (2), including data necessary for the identification of such person (name or names, surname and contact details).

The application for obtaining an operating licence shall be submitted to the State Institute of Drug Control which is entitled to decide on granting authorization to the applicant within 90 business days after receiving the request (Articles 18-19)

In its decision the Institute shall indicate the scope of activities and type of tissues and cells for which the permit is issued for. The State Institute for Drug Control is also entitled to impose specific obligation or set out special conditions in its decision with regard to the specific nature of tissues and cells, or their use or the specific nature of the procedures (Article 19).

The State Institute for Drug Control may require further information and documentation for its decision and it is also entitled to carry out on-site inspection in order to verify the facts contained in the application. At the time of writing the present report 19 tissue banks, seven transplantation centers, 15 genetic laboratories, 22 hospital blood banks, and 18 ICF centers have been identified that can be considered as biobanks in the wide sense.

3. PECUNIARY ASPECTS

Cord blood haematopoietic stem cells are considered to be part of the human body and as such Article of 21 of the Oviedo Convention applies, stating that “the human body and its parts shall not, as such, give rise to financial gain.” Moreover, Article 2 of the Additional Protocol states that “The provisions of this Protocol applicable to tissues shall apply also to cells, including haematopoietic stem cells.” In addition to the above Article 28 of the Transplantation Act provides the prohibition of all forms of financial gain in relation to organ and tissue transplantations.¹⁶ Furthermore Article 7 of the Human Tissues and Cells Act also sets out that the operator of the tissue establishment is obliged to ensure that the tissue and cell donation is not subjected to financial imbursement, nevertheless a donor can receive a refund for efficiently, economically and demonstrably incurred expenses related to the donation process.

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

Where it is not possible to obtain consent from the donor, in practice and in lack of a specific piece of national legislation, the Convention on Human Rights and Biomedicine and the Data Pro-

¹⁶ Information is based on *Replies to the questionnaire for member states on organ trafficking*, Strasbourg, 2 June 2004, [bioethics/textes publics/CDBI/INF/2004/ CDBI/INF (2003) 11 rev. 2 INF(2003)11rev2 e organ trafficking replies. Steering Committee on Bioethics (CBDI), European Health Committee (CDSP) Available at: [http://www.coe.int/t/dg3/healthbioethic/Activities/05_Organ_transplantation_en/CDBI_INFv\(2003\)11rev2.pdf](http://www.coe.int/t/dg3/healthbioethic/Activities/05_Organ_transplantation_en/CDBI_INFv(2003)11rev2.pdf)

tection Act regulate the matter. Practice developed the rule that DNA samples are treated like sensitive data,¹⁷ while in positive law Article 4 Point b) of the Data Protection Act introduces the category of sensitive data, which among others include health status and biometric data.

According to the general rule laid down in Article 5 Section (2), the data controller or processor may only process personal data with the consent of data subject. Without such consent, the controller may process the data:

- (a) if carrying out processing which is essential to comply with legal obligation of the controller;
- (b) if the processing is essential for the fulfilment of a contract to which the data subject is a party or for negotiations on conclusion or alteration of a contract negotiated on the proposal of the data subject;
- (c) if it is essential for the protection of vitally important interests of the data subject. (In this case, the consent of data subject must be obtained without undue delay.);
- (d) that were lawfully published in accordance with special laws; or
- (e) if it is essential for the protection of rights and legitimate interests of the controller, recipient or third persons;
- (f) if personal data of public figures are provided that reveal information on their public activity or their functional or working position; or
- (g) if the processing has solely archival purposes based on a special Act.

In relation to Points d), e) and g), the Act specifically states that data processing may not infringe the right to privacy of the data subjects.

According to Article 5 Section (4) before consenting the data subject must be provided with the information about the purpose of processing, the types of personal data to be processed, who the controller or processor is and the period of time the consent is being given for. The controller or processor must be able to prove the consent of data subject to personal data processing during the whole period of processing.

Transfer of data to another controller is only permissible, if – as laid down in Section (6) – the data on the data subject were acquired in relation to activities of the controller or the data in question consist in published personal data; the data are used exclusively for the purpose of offering business opportunities and services; or the data subject has been notified in advance of this procedure and he or she has not expressed disagreement with this procedure. The controller or processor to whom data pursuant to the previous Section have been transferred may not transfer these data further.

Articles 9-11 lay down the special rules of consent in relation to sensitive data. In line with Article 9 sensitive data may be processed only if the data subject has given his or her express consent to the processing. When giving consent, the data subject

¹⁷ Lukáš Prudil and Josef Kuře, Research Ethics Committees in the Czech Republic in Deryck Beylveid, David Townend and Jessica Wright (eds.), *Research Ethics Committees, Data Protection and Medical Research in European Countries*, Aldershot: Ashgate, 2005, 34.

must be provided with the information about the purpose of processing, furthermore what personal data, which controller and what period of time the consent is being given for. The controller must be able to prove the existence of the data subject's consent to personal data processing during the whole period of processing. The controller is obliged to instruct in advance the data subject of his or her rights pursuant to Articles 12 on the data subject's access to information and Article 21 discussed *infra*. Sensitive data may also be processed, if necessary in order to preserve the life or health of the data subject or some other person or to eliminate imminent serious danger to their property, if his or her consent cannot be obtained, in particular, due to physical, mental or legal incapacity, or if the data subject is missing or for similar reasons. The controller shall be obliged to terminate data processing as soon as the above mentioned reasons cease to exist and must liquidate the data, unless the data subject gives consent to further processing. Without giving an exhaustive list of instances when sensitive data may be processed, it is crucial to mention Points c) and f) of Article 9 which permits sensitive data processing in relation with ensuring health care, public health protection, health insurance, and the exercise of public administration in the field of the health sector pursuant to a special act, or if data processing is related to the assessment of health in other cases provided by a special act; or if the data processed pursuant to a special act are necessary to carry on health insurance, social insurance (security), state social support and

other state social benefits, social care and social and legal protection of children, and if, at the same time, the protection of these data is ensured in accordance with the law. Sensitive data may also be processed exclusively for archival purposes pursuant to a special act.

According to Article 11 when collecting personal data the controller shall be obliged to inform the data subject of the scope and purpose of data collection, processing; who and in what manner will process the personal data and to whom the personal data may be disclosed. Information about the above can only be avoided if the data subject is already aware of this information. The controller must inform the data subject about his or her right to access to personal data, the right to have his or her personal data rectified as well as other rights provided for in Article 21 discussed *infra*. The Act differentiates between cases when data are acquired from the data subject directly from cases when data have not been obtained from the data subject. First, whenever information are acquired directly from the data subject, he or she also has to be informed about whether the provision of the personal data is obligatory or voluntary. Should the data subject be obliged by a special act to provide personal data, the controller has to instruct him or her about this fact as well as about the consequences of refusal to provide the personal data. Second, if the personal data were not obtained from the data subject the controller is not obliged to provide the information and instruction mentioned above, if other conditions are also fulfilled, i.e. if personal data are pro-

cessed exclusively for the purposes of state statistical service, scientific or archival purposes and the provision of such information would involve a disproportionate effort or inadequately high costs; or if storage on data carriers or disclosure is expressly provided by a special Act; or if personal data processing is imposed on the controller by a special Act or such data are necessary to exercise the rights and obligations ensuing from special acts; or if exclusively lawfully published personal data are processed; or if the controller is processing personal data obtained with the consent of data subject.

Article 12 already touched upon, is devoted to the data subject's right to access to information. Should the data subject request information on the processing of his or her personal data, the data controller or processor shall be obliged to provide him or her with this information without undue delay. The contents of the information are listed as follows: the purpose of personal data processing; the personal data or categories of personal data that are subject of processing including all available information on their source; the character of the automated processing in relation to its use for decision-making, if acts or decisions are taken on the basis of this processing the content of which is an interference

with the data subject's rights and legitimate interests; and the recipients or categories of recipients. The provision also allows the controller or processor to request a reasonable reimbursement not exceeding the costs necessary for providing the information.

The Czech law does not provide for a fixed age of "medical majority". A natural person's legal competency is governed by the Civil Code. According to Article 8 of the Civil Code majority is acquired by achieving the age of 18. Before this age, majority may only be reached through marriage.

In case of living donors there is a presumed refusal, i.e. a full informed consent is required and the protection of specific vulnerable groups is foreseen. As stated in Article 4 of the Transplantation Act, in case of transplantation of tissues and organs from minors or persons without legal capacities who according to their health status cannot consider the consequences of such intervention to their health, the explicit disapproval can be made by their legal representative or tutor.¹⁸ In case of deceased donors, the case is the opposite: consent is presumed, but anonymity of donors shall be guaranteed. The Transplantation Act has also established a register of persons who expressed their will of not to be subjected to transplantation after their death.¹⁹

¹⁸ Information is based on *Report on the Situation of Fundamental Rights in the Czech Republic in 2003*, January 2004, E.U. Network of Independent Experts on Fundamental Rights (CFR-CDF) Available at: <http://cridho.cpd.r.ucl.ac.be/documents/Download.Rep/Reports2003/R.Nationaux2003/CFR-CDF.repCzechRep.2003.pdf>

¹⁹ Information is based on *Report on the Situation of Fundamental Rights in the Czech Republic in 2003*, January 2004, E.U. Network of Independent Experts on Fundamental Rights (CFR-CDF) Available at: <http://cridho.cpd.r.ucl.ac.be/documents/Download.Rep/Reports2003/R.Nationaux2003/CFR-CDF.repCzechRep.2003.pdf>

5. ACCESS TO DATA AND SAMPLES AND ANONYMITY

The Data Protection Act as laid down by Article 3 applies to all personal data processing, both by automatic or other means, whether data are processed by state authorities, territorial self-administration bodies, other public authority bodies, or natural and legal persons.

The definitions of the Act mirror the wording of the Data Protection Directive. Personal data are “any information relating to an identified or identifiable data subject. A data subject shall be considered identified or identifiable if it is possible to identify the data subject directly or indirectly in particular on the basis of a number, code or one or more factors specific to his/her physical, physiological, psychological, economic, cultural or social identity” (Article 4 a)), while anonymous data are the ones “that cannot be linked to an identified or identifiable data subject in their original form or following processing thereof.” (Article 4 c)) The Act introduces the category of sensitive data, which among others include health status and biometric data. (Article 4 b))

In the field of biobanks and genetic research it is crucial to look into how data may be transferred among states. In line with Article 27 of the Data Protection Act the free flow of personal data shall not be restricted if data are transferred to a Member State of the European Union. As to non-Member States, the provision states that personal data may be transferred to third countries if the prohibition of restriction of the free movement of personal data is ensuing from an international treaty to the ratification of which the Parliament has given his assent and

which is binding the Czech Republic, or if the personal data are transferred on the basis of decision of an institution of the European Union. Further conditions to be met are the following:

- a) the data transfer shall be carried out with the consent of, or on the basis of an instruction by the data subject;
- b) in a third country, where personal data are to be processed, there shall be sufficient specific guarantees for personal data protection, e.g. by legal or professional regulations and security measures. Such guarantees may be specified in particular by a contract concluded between the controller and the recipient;
- c) the personal data concerned shall be part of publicly accessible data files on the basis of a special Act or they have to be on the basis of a special Act accessible to someone who proves legal interest; in such case the personal data may be disclosed only in the scope and under conditions provided by a special Act;
- d) the transfer has to be necessary to exercise an important public interest following from a special Act or from an international treaty;
- e) the transfer has to be necessary for negotiating the conclusion or change of a contract, carried out on the incentive of the data subject, or for the performance of a contract to which the data subject is a contracting party;
- f) the transfer shall be necessary to perform a contract between the controller and a third party, concluded in the interest of the data subject, or to exercise other legal claims; or finally

g) the transfer has to be necessary for the protection of rights or important vital interests of the data subject, in particular for rescuing life or providing health care.

Prior to the transfer of personal data to third countries, the controller is obliged to apply to the Office for authorization to the transfer, unless provided otherwise by a special Act. When considering the application, the Office has to examine all circumstances related to the transfer of personal data, in particular the source, final destination and categories of personal data which are to be transferred, the purpose and period of the processing, with regard to available information about legal or other regulations governing the personal data processing in a third country. When authorizing the transfer, the Office is obliged to specify the period within which the controller may perform the data transfers. Should changes occur in the conditions, the Office shall alter or revoke this authorization.

Stem cell research is covered by special legislation. According to Article 3 of Act 227/2006, research on human embryonic stem cells may be conducted only on the basis of a permission issued by the Ministry of Education, Youth and Sport, which is a unique solution in Europe. Research and accordingly storage are only possible on imported stem cell lines and on stem cell lines from surplus embryos from

Czech assisted reproduction centres with the written informed consent of the donor man and woman.²⁰ Embryos are not coded unlike other tissues and cells. Additionally, Article 18 of the Transplantation Act sets out the establishment of national health registries related to transplantation. The registries are managed by the Czech Transplantations Coordinating Centre (KST) established by the Czech Ministry of Health on the basis of the Transplantation Act. The KST is operated under the supervision of the Ministry and administer three national registries: (1) National Register of Patients Waiting for an Organ Transplantation; (2) National Register of Organ and Tissue Donors and (3) National Register of Organ and Tissue Transplantations.²¹ Stem cell lines are registered in one of the national registries.²²

Article 7 of the Human Tissues and Cells Act provides provisions considering the rights of the donor who provides samplers for tissue establishment. In line with the regulations as set out in Article 7, the operator of the tissue establishment shall ensure the identification of the donor during the procurement of tissues and cells and upon the written request of the donor, or his or her legal representative or close relatives to provide them with information on the donation and procurement procedure including information on the recording of donor's personal data and the protection thereof.

Articles 10-11 of the Human Tissues

²⁰ The Act also lays down the prohibition of cloning, and prescribes the registry of the stem cell lines. The Czech Republic is unique from a different point of view as well: surplus embryos are still being created, and may be used for research purposes.

²¹ Further information is available at: <http://www.kst.cz/web/home-en.php>

²² http://www.uzis.cz/info.php?article=13&mnu_id=7300&mnu_action=select&lng=cz

and Cells Act set forth the regulations on the import and export of tissues and cells between the Czech Republic and third countries and the distribution between the Czech Republic and the Member State of the European Union.

6. STORAGE

As mentioned in the previous point, the Data Protection Act as laid down by Article 3 applies to all personal data processing including biobanks.

According to Article 5 of the Data Protection Act the controller (i.e. the entity that carries out data processing and is responsible for such processing) or the processor has to specify the purpose and the manner of data processing. It has to collect personal data in an open manner. Collecting data under the pretext of some other purpose or activity is prohibited. The controller may process only accurate personal data obtained in accordance with the Data Protection Act. If necessary, the controller is obliged to update the data. The collection of personal data always has to correspond to a specified purpose in an extent necessary for fulfilment of the specified purpose. The same principles apply to storage, i.e. personal data may only be stored for a period of time that is necessary for the pre-defined purpose of processing. After expiry of this period, personal data may be stored only for statistical, scientific and archival purposes, but even in these cases the right to the protection of private and personal life of the data subject from unauthorised interference shall be respected, and personal data have to be made anonymous as soon as possible. Similarly to

collection and storage, personal data processing has to be in accordance with the purpose for which the data were collected. Personal data may be processed for some other purpose only within the limits of the provisions of Article 3 Section (6) on public security and defence and only if the data subject consented to further use of his or her personal data in advance. The controller has to ensure that personal data that were obtained for different purposes are not grouped.

According to Article 9 Point c) sensitive data processing in relation with ensuring health care, public health protection, health insurance, and the exercise of public administration in the field of health sector pursuant to a special act is permitted, similarly to the situation if data processing is related to the assessment of health in other cases provided by a special act.

In line with Article 10 whenever personal data are being processed, the controller and the processor have to ensure that the rights of the data subject are not infringed upon, in particular, the right to human dignity, and the private and personal life of the data subject are protected against unauthorised interference are respected.

The obligations of the controller and the processor in securing personal data are laid down in Article 13: they are obliged to adopt measures preventing unauthorised or accidental access to personal data, their alteration, destruction or loss, unauthorised transmission, other unauthorised processing, as well as other misuse of personal data. The controller or the processor are also obliged to develop and to document the technical-organisational measures adopted and implemented

which ensure personal data protection.

Articles 14 and 15 lay down the obligations of the employees of the controller or processor and other persons who process personal data on the basis of an agreement with the controller or processor. They may only process personal data under the conditions and within the scope specified by the controller or the processor, and they are obliged to maintain confidentiality of personal data and security measures whose publishing would endanger the security of personal data. Employees are obliged to comply with this requirement even after the termination of the employment or the relevant work.

Article 20 is dealing with the last phase of storage, i.e. liquidation of personal data. Accordingly the controller and the processor are obliged to carry out liquidation of personal data as soon as the purpose for which personal data were processed ceases to exist or on the basis of a request by the data subject pursuant to Article 21 to be discussed *infra*. The rule does not apply in case special Acts provide for exceptions relating to the preservation of personal data for archival purposes and to the exercising of rights in civil judicial proceedings, criminal proceedings and administrative proceedings.

The mentioned Article 21 allows each data subject who finds or presumes that the controller or the processor is carrying out processing of his or her personal data which is in contradiction with the protection of private and personal life or is in contradiction to the law, in particular if the personal data are inaccurate regarding the purpose of their processing, to do the following: either ask the controller or pro-

cessor for explanation; or require from the controller or processor to remedy the arisen state of affairs. It can mean in particular blocking, correction, supplementing or liquidation of personal data. Should the request of the data subject be justified, the controller or processor is obliged to remedy the situation. Should the controller or processor not satisfy the data subject's request, the data subject is entitled to appeal directly to the Personal Data Protection Office. The data subject may simultaneously make a request under Article 21 and appeal directly to the Office. If a breach of obligations provided by law occurs in the course of processing of personal data by the controller or by the processor, they are liable jointly and severally. Finally, the controller is obliged to inform the recipient without undue delay about the request of the data subject pursuant to the above provision and on the blocking, correction, supplementing or liquidation of personal data, except in cases where informing the recipient is impossible or would involve disproportionate effort.

According to Article 3 of Act 296/2008 on Safeguarding the Quality and Safety of Human Tissues and Cells, individuals handling tissues and cells are required to limit associated risks of the usage of tissues and cells in humans. The Human Tissue and Cells Act also sets out that in the event of serious adverse events, reactions or the suspicion of other potential adverse effects the aforementioned individuals are obliged to take all available measures to ensure remedy and to limit the adverse effects to the lowest possible level, as well as to provide information in accordance with the

introduction and application procedures referred to in Section 3 Point e) on the condition that the procedures do not breach data protection regulations. In line with the above mentioned provisions of the Human Tissues and Cells Act, Article 3 Section (3) also sets forth that operators of medical facilities who procure human tissues and cells shall monitor the serious adverse events, serious adverse reactions or the occurrence of other potential adverse effects; the operator also notifies, assesses and records of such serious adverse events, reactions and suspicion thereof and provide data about them without delay, while ensuring that the adverse impacts of these events, reactions remain at the lowest possible level; the operator shall also ensure protection of personal data including genetic information collected in compliance with the Act so that the donor and recipient could be identified. The operator of medical facilities are also obliged to maintain and preserve the records of tissues and cells to enable traceability of the activities undertaken thereon in a way which does not breach data protection. In addition to this traceability must be assured for at least 30 years after the use of tissues and cells. Finally in line with Article 3, the operator is also obliged to introduce and apply certain procedures for providing information, which does not breach data protection as well as to provide measures against illegal provision of information, including information for traceability and quality control and safety.

As it is mentioned above, the Human Tissues and Cells Act is primarily

a technical norm on quality assurance, storage, and traceability of the procurement of human tissues and cell. Thus Article 5 of the Act sets out special provisions on the technical requirements for tissue establishments. In line with Article 5, the operator of the tissue establishment is obliged to establish and maintain a quality system in order to meet the appropriate security requirements. The operator is also obliged to locate and identify all relevant data relating to the selection and use of any products and materials coming into contact with tissues and cells. Additionally, the operator is also obliged to establish and maintain a system for identification and traceability of tissues and cells, and donors. Such system also has to contain the origin of each donor, each donation and the tissues and cells, each package of tissues and cells during their collection, processing, upon release and distribution, or elimination, as well as the products and materials coming into contact with tissues and cells, and all legal and natural persons conducting business which the operator. Furthermore the aforementioned system for identification and traceability has to be capable to create unique codes for identification of the donation and the final packaging of tissues and cells. Article 5 also provides that the operator is obliged to set out procedures and conditions that guarantee the maintenance of quality and safety of tissues and cells in their distribution and the procedures as well as the conditions for accurate and rapid withdrawal of proven distributed tissues and cells from further use.

7. SUPERVISION, COMPENSATION, PENALTIES

Ethics committees are established and managed at the healthcare institutions where research is conducted, by a regional office or the Ministry of Health. The Ethics Committee of the Ministry of Health also functions as an advisory body to the Ministry.²³ There are two national bioethics committees in the Czech Republic, the Central Ethics Committee of the Ministry of Health of the Czech Republic²⁴ and the Bioethical Commission of the Research and Development Council. In addition to the aforementioned ethical committees operated at the national level, upon the recommendation of the Ministry of Health local ethics committees have been established.²⁵

The Central Ethics Committee was established by the Ministry of Health in 1990 as an advisory body which gives opinions and recommendations on ethical issues to the Ministry. The Bioethical Commission represents an expert and advisory body associated to the Research and Development Council. The Bioethical Commission was established in 1997 as a group of experts with the aim of preparing proposals on the bioethical aspects of research and development in the field of modern

biology and medicine.²⁶ With regards to Act No. 227/2006 Coll. on Research on Human Embryonic Stem Cells a new Bioethical Commission of the Research and Development Council was founded in September 2006 in line with Article 35 of Act No. 130/2002 Coll., on Research and Development Support from Public Funds and on the Amendment to Some Related Acts (Research and Development Support Act). Specific ethics committees can be established upon a researcher's application and after approval has been granted by the State Institute for Drug Control.²⁷

The hierarchy and relation of the ethics committees to each other are not clarified. Although all these ethics committees can give advice on medical research, the legal force of these opinions remains unclear. Once a medical research is being evaluated, ethical committees are supposed to review the ethical acceptability, scientific feasibility and the related legal issues. Ethics Committees are following a certain practice where they mainly subject the research in question to a legal review. Laws are however, as it has been proven above, deficient, missing, and the ones in existence are in constant change, which makes the work of the committees especially burdensome. Therefore they mainly base their

²³ Lukáš Prudil and Josef Kuře, Research Ethics Committees in the Czech Republic in Deryck Beyleveld, David Townsend and Jessica Wright (eds.), *Research Ethics Committees, Data Protection and Medical Research in European Countries*, Aldershot: Ashgate, 2005, 32.

²⁴ Centralni Eticka Komise Pri Ministerstvu Zdravotnictvi Ceske Republiky

²⁵ Further information is available at: <http://www.privireal.org/content/rec/czechrepublic.php>

²⁶ According to the website of the Bioethical Commission of the Research and Development Council, the proposals thereof is mainly considered the question of moral and legal aspects of the investigation of human genome, genetically modified organisms, genetical testing and therapy and also experiments dealing with in vitro fertilisation, transplantation of the fetal tissue, xenotransplantations, genome patent applications and many others.

²⁷ Further information is available at: <http://www.sukl.cz/index.php?lchan=1&lred=1>

opinions on the best established and relatively constant law, the Data Protection Act. They review the researchers, the facility where research is conducted, informed consents, insurance, possibility of compensation, contracts, remunerations, etc.²⁸ Ethics committees have the power to decide, i.e. to accept or reject applications. Should a research not follow the conditions, the research approval will be withdrawn and the research activity immediately has to come to a halt. Should a research project have been started without approval, fines may be imposed by the judiciary. Sanctions may also be imposed by the employer, the Medical Chamber or in extreme cases of violations of the law, courts may also apply criminal sanctions.²⁹ In relation to extreme cases the Transplantation Act introduced a new form of criminal offence in the Penal Code in 2002 according to which Article 209a sets out provisions against unauthorised handling of tissue or organs. According to Article 209a, an individual who in contravention of the Transplantation Act removes from the body of a deceased person a sample of tissue or an organ, will be punished by imprisonment of up to two years or by a ban on activity. Any other person will be sanctioned in this same manner who, in the expectation of gain for him-

or herself or another person, handles human tissue or human organs removed in contravention of special legal regulations. Article 209a aims only at dealing with the unauthorised removal of tissue or organs from the body of a dead person and with unauthorised handling of already removed tissue or organs and does not intend to cover unlawful removal of tissue or organs from living persons, as such cases are already covered by a wide variety of provisions as set out in the Penal Code. The type of the applicable criminal offence depends on the form of criminal liability and the caused consequences – from oppression, concerning which resultant bodily harm is absent, to “light” bodily harm, or wilfully causing grievous bodily harm, right up to murder.³⁰ Nevertheless, the most significant legislative instrument in the respective legal domain is Act No. 296/2008 Coll. on Human Tissues and Cells which provides special regulative framework in relation to the donation, procurement and testing of human tissues and cells. According to Article 15 of the Human Tissues and Cells Act the State Institute for Drug Control operates as supervisory authority under the provisions of the Act and it is entitled to grant operating licences to the operators of tissues establishments. In addition to the above the Ministry of

²⁸ Lukáš Prudil and Josef Kuře, Research Ethics Committees in the Czech Republic in Deryck Beylveeld, David Townend and Jessica Wright (eds.), *Research Ethics Committees, Data Protection and Medical Research in European Countries*, Aldershot: Ashgate, 2005, 32.

²⁹ Lukáš Prudil and Josef Kuře, Research Ethics Committees in the Czech Republic in Deryck Beylveeld, David Townend and Jessica Wright (eds.), *Research Ethics Committees, Data Protection and Medical Research in European Countries*, Aldershot: Ashgate, 2005, 33.

³⁰ Information is based on *Replies to the questionnaire for member states on organ trafficking*, Strasbourg, 2 June 2004, [bioethics/textes publics/CDBI/INF/2004/ CDBI/INF (2003) 11 rev. 2 INF(2003)11rev2 e organ trafficking replies. Steering Committee on Bioethics (CBDI), European Health Committee (CDSP). Available at: [http://www.co.e.int/t/dg3/healthbioethic/Activities/05_Organ_transplantation_en/CDBI_INF\(2003\)11rev2.pdf](http://www.co.e.int/t/dg3/healthbioethic/Activities/05_Organ_transplantation_en/CDBI_INF(2003)11rev2.pdf)

Health has the competence to decide on appeals against decisions issued by the State Institute for Drug Control under the Human Tissues and Cells Act.

The State Institute is entitled to monitor the occurrence and evaluation of major adverse reactions, serious adverse events at tissue establishments in line with the provisions of the Act. The Institute also prepares annually a report on the registered serious adverse reactions and events to the European Commission. The State Institute is entitled to decide in cases of doubt, whether the processing, storing and distribution of tissues and cells are in compliance with the provisions of the Human Tissues and Cells Act.

Article 21 of Act 296/2008 also sets out that the State Institute for Drug Control is entitled to verify whether the testing procedure conducted on human tissues and cells is carried out in compliance with the Human Tissues and Cells Act. On the basis of the provisions of the above mentioned Act, the State Institute is also entitled to carry out laboratory testing of samples in healthcare facilities at least once every 2 years or in case if there has been or is suspected that there was a serious adverse reaction or serious adverse events.

Article 25 of the Human Tissue and Cells Act provides the relevant provisions on administrative offences committed by individuals and legal entities in relation to tissues and cells.³¹ In line with Article 25 Section (3) the operator of a tissue establishment commits an administrative offence if he or she fails

(1) to provide notification, assessment and recording of serious adverse events or reactions; (2) or fails to provide anonymous data, including genetic information collected in compliance with the Act so that the donor and recipient could be identified; (3) or to ensure traceability for at least 30 years after the use of tissues and cells.

Section (4) also provides that the operator of the tissue establishment commits an administrative offence if he or she fails to comply with (1) the notification requirements on the risk of disease transmission and other potential adverse effects; or (2) fails to provide the records on reconstruction of the conditions, implementation, evaluation and conclusions of the audit, additionally these records must be in compliance with traceability, and provide information on the range of quality controls and safety requirements for their implementation, including laboratory-scale testing of samples from donors and the requirements for their implementation, and record keeping for the implementing legislation. According to Section (4) an administrative offence is deemed to be committed by the operator if he or she (3) fails to ensure that the tissues and cells procurement is carried out by persons who are older than 18 years of age, having legal capacity and qualified for a particular type of activity in accordance with the legal requirements; (4) or carries out activities contrary to the activities authorized by the Act.

Section (5) sets out that the operator of the tissue establishment also commits an administrative offence if he or

³¹ For detailed provisions see Article 25 of Act 296/2008.

she fails to provide a system for identification and traceability for tissues and cells, and donors, and to that end, each donor, each donation and each pack of tissues and cells, from which it originates, is assigned a unique code; furthermore the operator is also obliged to provide each package of tissues and cells during their collection, processing, upon release and distribution, or elimination, as well as a database on the products and materials coming into contact with tissues and cells, and furthermore on all legal and natural persons conducting business, which he or she supplied with or has taken from tissue and cells; and finally he or she is also obliged to record the way for creating unique codes for identification of the donation and the final packaging of tissues and cells. The administrative offense shall be imposed a fine from 500.000 up to 3.000.000 CZK depending on the type of the committed offences.

The background legislation always to be invoked in relation to the regulation of biobanks is the mentioned Act 101/2000 of 4 April 2001 on Personal Data Protection. Article 2 established the Personal Data Protection Office as a supervisory authority within the meaning of Article 28 of the Data Protection Act.³² The Office for Personal Data Protection is an independent body supervising the observance of rules on personal data processing, dealing with individual complaints, providing information and organizing consultations on data protection, furthermore it maintains a register of instances of notified personal data processing. In line with Article 31 it per-

forms its activities on the basis of a control plan or on the basis of the incentives and complaints.

Registrations are obligatory: according to Article 16 Section (1) whoever intends to process personal data as a data controller has to notify the Office about this intention. Such registration notification may be submitted electronically with the help of a registration form to be downloaded from the Office's web site.

Should a justified concern arise in relation to the notification that the Data Protection Act might be breached in processing of personal data, the Office shall initiate proceedings in line with Article 17 at its own instigation. Should the Office find that the controller breaches the conditions provided by the Data Protection Act, it shall decide according to Article 17a on the revocation of the registration. If the purpose for which the processing was registered ceased to exist, the Office shall decide on the revocation of the registration either on its own instigation or on request of the controller.

Article 18 provides some exceptions when notification is not needed. These include cases when personal data in question are

- a) part of data files publicly accessible on the basis of a special Act;
- b) imposed on the controller by a special Act or when such personal data are needed for exercising rights and obligations following from a special Act; or
- c) in case of processing that pursues political, philosophical, religious or trade-union aims carried out within

³² In original language: Urad pro ochranu osobnich udaju, for further details please visit www.uouu.cz

the scope of legitimate activity of an association and which relates only to members of the association or persons with whom the association is in recurrent contact related to a legitimate activity of the association, and the personal data are not disclosed without the consent of data subject.

According to Article 25 the general rules of liability for damage apply to matters not specified by the Data Protection Act. In the following, measures for remedy and the penalties will be listed. In line with Article 40 if a controlling person finds that obligations imposed by the Data Protection Act have been breached, the inspector shall determine which measures shall be adopted in order to eliminate the established shortcomings and set a deadline for their elimination. If liquidation of personal data has been ordered, the relevant personal data shall be blocked until their liquidation. The controller may submit an objection to the President of the Office against ordering of such liquidation. The personal data must be blocked until a decision on the objection is made. An administrative review is possible against the decision of the President. The data have to remain blocked until a decision is made by the court. The controlled person is obliged to submit a report on the adopted measures within the deadline. In line with Article 41 the Administrative Code shall govern all the above proceedings. Articles 44-46 are dealing with penalties. According to Article 44 Section (1) a breach occurs if confidentiality requirements have been infringed by a natural person who

(i) is in a labour or similar relationship to the controller or processor; or who (ii) carries out activities for the controller or processor on the basis of an agreement, or who (iii) in the framework of fulfilling powers and obligations imposed by a special Act comes into contact with personal data kept by the controller or processor. A fine up to CZK 100.000 may be imposed in such cases.

A graver offence is committed if a natural person in the position of the controller or processor

- a) fails to specify the purpose, means or manner of processing or breaches an obligation by the specified purpose of processing or exceeds his or her authority ensuing from a special Act;
- b) processes inaccurate personal data;
- c) collects or processes personal data in a scope or manner which does not correspond to the specified purpose;
- d) preserves personal data for a period longer than necessary for the purpose of processing;
- e) processes personal data without the consent of data subject except the cases provided by law;
- f) fails to provide the data subject with information in the scope or in the manner provided by law;
- g) refuses to provide the data subject with the requested information;
- h) fails to adopt or implement measures for ensuring security of personal data processing;
- i) fails to fulfil the notification obligation pursuant to this Act;
- j) jeopardises a substantial number of persons by unauthorized interference in the private and personal life;

- k) fails to fulfil obligations related to the processing of sensitive data; or
- l) fails to fulfil obligations related to the processing of sensitive data.

For offences a)-i) a fine up to CZK 1,000,000, while for offence listed in points j)-k) a fine up to CZK 5,000,000 may be imposed.

Article 45 dealing with other administrative delicts lays down that legal or natural persons carrying on business according to special regulations when processing personal data in the position of the controller or processor commit an administrative delict if they commit any of the above breaches. A fine up to CZK 5.000.000 may be imposed for an administrative offence pursuant Points a)-i) and a fine up to CZK 10.000.000 may be imposed for an administrative offence pursuant to the administrative delicts in Points j)-l).

According to Article 46 a legal person shall not be liable for an administrative delict if he proves that he has made best efforts reasonable to be required

to prevent the breach of a legal obligation. There is a statute of limitation in Section (3): liability of the legal person for an administrative delict becomes extinct, if the administrative body has not initiated proceedings within 1 year from the day when it learned of it, but not later than within 3 years from the day when the delict was committed. Should a fine be imposed, it is payable within 30 days as of the day when the decision on imposing the fine came into force, in line with Section (6). According to Section (7) the fine shall be collected by the Office and enforced by the locally competent regional financial authority pursuant to a special Act. The revenue from fines will be a part of the income of the state budget.

8. PUBLIC DEBATE

The regulation of biobanks did not invoke a public debate in the Czech Republic. The controversies have been discussed in professional circles mainly.

II. FORENSIC BIOBANKS

1. RELEVANT LAWS

There is no specific law on forensic databanks in the Czech Republic.

The main laws applicable are the Penal Code, i.e. Act No. 140/1961 Coll., as amended;³³ the Penal Procedural Code, i.e. Act No. 141/1961 Coll., as amended,³⁴ both entering into force in 1962; and Act 273/2008 on the Police,³⁵ especially Article 65 thereof on the obtaining of personal data for future identification. Of course the above mentioned Data Protection Act is also of great relevance.³⁶

Partly because the Data Protection Act follows the Data Protection Directive, some of the most crucial provisions do not seem to extend to the criminal law area. According to Article 3 Section (6) crucial obligations of the controller and the provisions on informed consent, furthermore on the data subject's access to information are not applicable if the controller ensures (a) security of the Czech Republic, (b) defence of the Czech Republic, (c) public order and internal security, (d) prevention, investigation, detection and prosecution of criminal offences, (e) important economic interest of the Czech Republic or of the European Union, (f)

important financial interest of the Czech Republic or of the European Union, or (g) exercises control, supervision, surveillance and regulation related to exercise of public authority when ensuring public order, internal security, persecution of offenses, economic or financial interests of the Czech Republic or the European Union, or (h) activities related to disclosure of files of the former State Security.

Despite these exceptions, there are still a number of provisions which may be applicable in relation to the field of forensic biobanks. The definitions of the Act mirror the wording of the Data Protection Directive. Personal data are "any information relating to an identified or identifiable data subject. A data subject shall be considered identified or identifiable if it is possible to identify the data subject directly or indirectly in particular on the basis of a number, code or one or more factors specific to his or her physical, physiological, psychological, economic, cultural or social identity" (Article 4 a)), while anonymous data are the ones "that cannot be linked to an identified or identifiable data subject in their original form or following processing thereof." (Article 4 c)) The Act introduces the category of sensitive

³³ In original language: Zákon č. 140/1961 Sb., trestní zákon.

³⁴ In original language: Zákon č. 141/1961 Sb., o trestním řízení soudním (trestní řád).

³⁵ In original language: Zákon č. 273/2008 Sb., o Policii České republiky.

³⁶ In original language: Zákon č. 101/2000 Sb., o ochraně osobních údajů.

data, which among others include conviction of a criminal act, health status and biometric data. (Article 4 b))

2. MANAGEMENT AND SUPERVISION

It is the police that manages the Czech forensic databank³⁷ and the Office for Personal Data Protection supervises it.³⁸ The Czech National DNA database³⁹ having its seat in Prague became operational in mid 2002 with the objective to detect and prevent crime. The Czech legislator opted for the CODIS (Combined DNA Index System).

3. SAMPLES AND SAMPLE TAKING, CONSENT

According to Article 114 Section (2) of the Act on Penal Proceeding, the taking of biological sample is not considered as an intrusion into the bodily integrity. Preferably sample taking shall happen with the consent of the person concerned or with the consent of the organ involved in criminal investigation, unless sample taking would cause a danger to the health of the respective person. Samples taken from suspects and convicts are buccal swab or blood. Buccal swab taking may be conducted by the police or a health care professional, i.e. a physician or a health care

worker. According to Section (3) of the same Article the person from whom sample is to be taken, has the duty to cooperate, otherwise in line with Section (4) adequate force may also be used.

The age of criminal responsibility is 15 years in the Czech Republic and the same rules apply to suspects and convicts between 15-18 years of age than to adults in terms of taking samples.

Samples are only collected from persons suspected of having committed graver crimes or from convicts who have been proven to committed such.

In relation to sample taking, Article 65 of the Police Act also sets out that the police, in order to carry out its tasks for future identification, is entitled to scan fingerprints, to identify physical characteristics, body measurements, to make video, audio, and similar records and to collect biological samples, by providing information on genetic characteristics. Persons from whom samples may be taken include persons accused of committing an intentional crime, persons serving a prison sentence for committing a deliberate crime, persons who are in security detention, or wanted persons who have been found. Article 79 of the Police Act also provides that the police may process personal data including sensitive information without the consent of the data subject if it is necessary to carry out its tasks. Personal da-

³⁷ <http://www.policie.cz/kriminalisticky-ustav-praha.aspx>

³⁸ <http://www.uoou.cz>

³⁹ It is worthwhile to mention the Forensic DNA Service (<http://dna.com.cz>) which is a genetic genealogy company that provides its services in the field of forensic paternity DNA analysis or DNA extraction from bone samples. Another DNA testing company is the Genomac (<http://www.genomac.cz/>) which is a competitor of the aforementioned company. Further details are available on the privacy issues in relation to DNA services in the Czech Republic. See <http://www.eyeeondna.com/2007/06/21/dna-testing-in-the-czech-republic/>

ta on racial origin, religious or political beliefs, membership of the association or sexual behaviour, shall be processed by the police only if necessary for a particular criminal proceeding.

Furthermore Article 80 of the Police Act declares that the police is entitled to transmit or make available personal information (a) if it is provided by the Police Act or other legislation or international treaty directly applicable regulation of the European Communities; (b) or if the data transfer or disclosure is necessary to remove a serious threat for the safety of persons or public order or (c) if the interests of the data subject requires to do so. In the case referred to in point a) personal data may be transmitted to the recipient without a request, unless another law, international treaty or a directly applicable European Community regulations differently. In the case referred to in Point c) the transfer of personal data may proceed only upon a written request, which must include the purpose for which personal data to be transmitted.

4. PURPOSE AND SCOPE OF COLLECTION

According to Article 65 of the Act on the Police, the sole aim of sample taking is obtaining personal data for future identification. In this light it is interesting that both the above mentioned Article 114 and Article 65 of the Act on Penal Proceeding itself mention not only suspects but also persons convicted from whom samples shall be taken.

Article 81 of the Police Act also sets forth that the police may disclose personal information (a) to the extent nec-

essary to perform its duties in order to ensure the security of the Czech Republic, in order to find lost persons or for the prevention and detection of crime, or (b) for the purposes of preventing and avoiding serious threat to public order and safety.

5. ACCESS TO DATA AND SAMPLES

Article 80 of Act 273/2008 on the Police on the transmission and disclosure of personal data makes a reference to international treaties adopted on the exchange of data. Accordingly the police transmits or makes available personal information if provided for by the Police Act or other legislation, international treaty or piece of legislation of the European Union. Data transfer or disclosure are permissible if necessary to remove a serious threat to the safety of persons or to public order, or if it was in favour of the person to whom personal data relates.

According to Article 80 Section (4) false or inaccurate data may not be transferred. Should uncertified personal data be transferred, the degree of reliability has to be marked. Should it turn out that false or inaccurate personal data had been transferred, the police shall inform the recipient of that fact with undue delay.

In line with Article 80 Section (5) the recipient of personal data is entitled to process personal data only for the purposes for which the data has been transmitted or been made available.

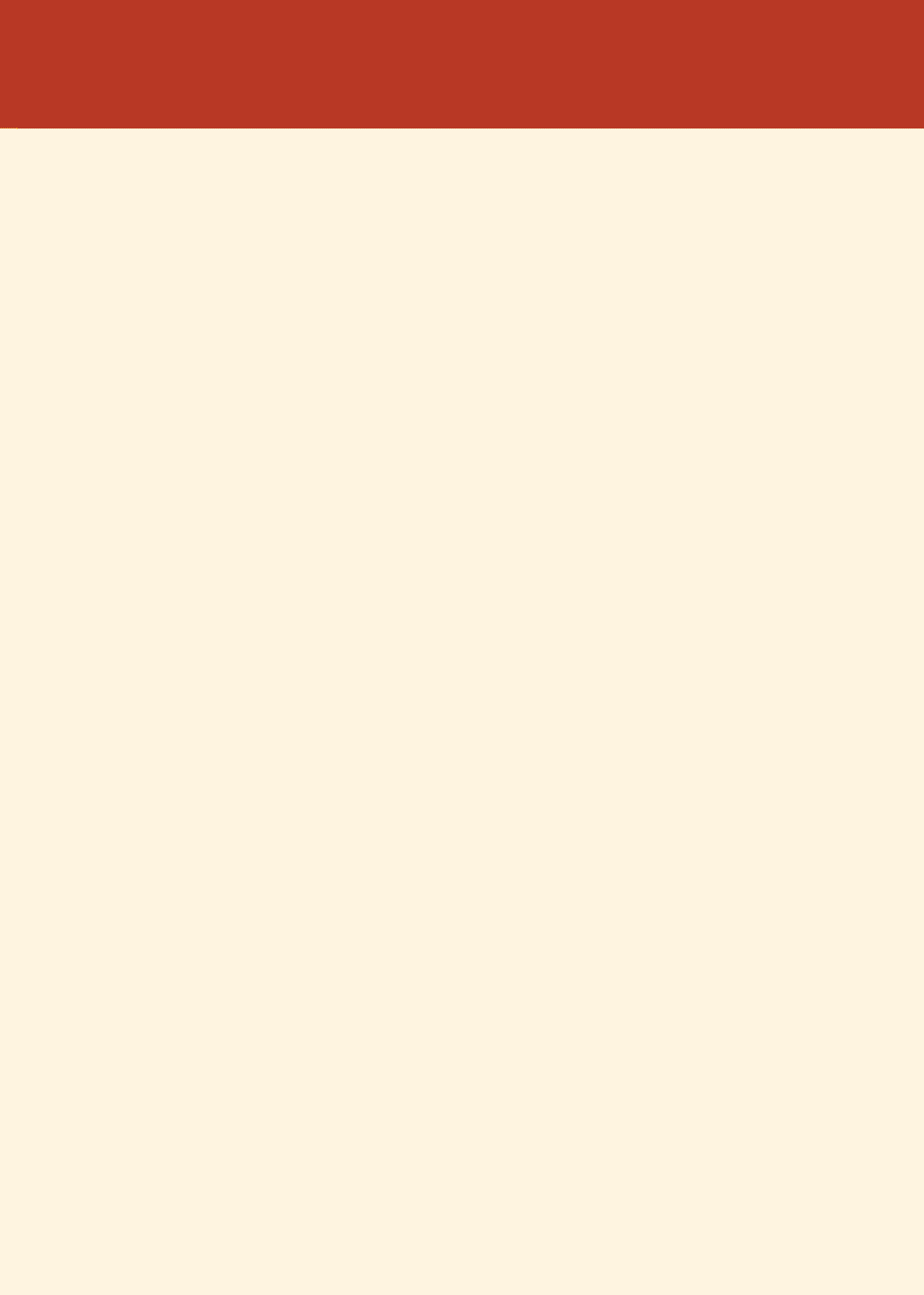
Section (6) of Article 80 contains an almost word-by-word reference to police cooperation in criminal matters and the Prüm Treaty.

Article 83 of the Police Act also provides that the police upon the written request of the data subject shall provide the applicant with the collected personal information relating to his or her person free of charge, within 60 days of receipt of the application. Furthermore, Article 87 of the Police Act sets out that the police shall keep personal information for the purposes of Article 85 as long as necessary for the purpose of their processing. Should the purpose lapse, personal information needs to be destroyed.

6. STORAGE

According to Articles 85-86, personal data may be collected, processed, combined and stored for crime prevention, detection and prosecution purposes, in order to ensure the security of the Czech Republic, public order and internal security. According to Article 79, the police can store personal data and even sensitive data without consent if those data are necessary for fulfilling the tasks of the police. Whenever

personal data are being processed, the purpose for procession has to be stated. According to Article 87, personal information for the purposes listed in Article 85 may only be kept as long as necessary for the purpose of processing. According to Article 82 on further processing of personal data, the necessity of storage for the fulfilment of police tasks has been reviewed at least every three years. Once the purpose expired, personal information, irrespectively whether stored on paper or in an electronic format, have to be destroyed. Also according to Article 5 Section (5) of Act 273/2008 on the Police, the police has the duty to destroy all personal data and stop processing them as soon as it is not necessary for the purpose of prevention, search and investigation of criminal activities or for the safety of the Czech Republic, public order or internal security. Interestingly, the cited provision only mentions the destruction of data, but not that of samples. According to Article 83, everyone has the right to ask the police to correct personal false or inaccurate personal data.





9 789638 853813