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JUDIT SÁNDOR  
MARCIN ŚLIWKA  
PETRA BÁRD

THE LEGAL REGULATION  
OF BIOBANKS

## National Report: Poland



CENTER FOR ETHICS AND LAW  
IN BIOMEDICINE





Editors: Judit Sándor and Petra Bárd

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Address: 1051 Budapest Nádor u. 9. Hungary

Telephone: +36-1-472-3403

Fax: +36-1-354-1599

E-mail: [celab@ceu.hu](mailto:celab@ceu.hu)

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

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## THE REGULATORY FRAMEWORK OF THE ESTABLISHMENT, MANAGEMENT AND FUNCTIONING OF BIOBANKS IN POLAND

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

Slovak Republic, and Slovenia. The present booklet is the first one in the series of country reports prepared by CELAB.

In order to familiarize ourselves with the situation how biobanks actually work, we visited the International Hereditary Cancer Center at the Pomeranian Medical University (ul. Polabska 4, 70-115 Szczecin) chaired by Prof. Jan Lubinski, MD, PhD. This Cancer Center has many parallel functions. It is one of the main biobanks in the field of cancer research in Central and Eastern Europe. In addition scientists from the Pomorska Akademia Medyczna (Pomeranian Medical Academy) in Szczecin, led by Professor Jan Lubiński provide numerous genetic tests and diagnosis to cancer patients but they also conduct research and develop patents for new types of genetic test. Genetic data in this biobank are processed for therapeutic, research and commercial purposes as well. We have also launched a questionnaire about the Polish legal framework and we received substantial help from Dr. Atina Krajewska, Dr. Anita Gałęska-Śliwka and Dr. Piotr Girdwojny.

*Budapest, 1 September 2009*

## I. CLASSICAL AND POPULATION BIOBANKS

### 1. DEFINITION OF BIOBANKS

In Poland there is no specific law on biobanks or on genetic data. Although the *Cell, Tissue and Organ Collection<sup>1</sup>, Storage and Transplantation Act* (Transplantation act) of July 1, 2005 (Dz. U. Nr 169, poz. 1411) contains rules concerning the establishment of tissue and cell banks. Furthermore the Public Blood Service Act 1997 (Dz. U. z dnia 11 września 1997 r.) regulates storage of blood but in *stricto sensu* they are not applicable to the research biobank.

The Transplantation Act defines in Article 2 the notion of “tissue and cell banks” in the following way:

“Tissue and cell bank means organizational unit that is handling collection, processing, sterilization, storage and distribution of tissues and cells. Units of that type may also recover and test tissues and cells.”<sup>2</sup>

It is clearly stated in Article 1 that the law is applicable to recovery, storage and transplantation of cells, including bone-marrow, haematopoietic cells, peripheral blood and umbilical cord

blood cells, tissues and organs from living donors and cadavers.

### 2. RELEVANT LAWS

Although there are recent initiatives for the foundation of a national biobank and an explicit intention that Poland will join the Biobanking and Biomolecular Resources Research Infrastructure (BBMRI) in the following years, the country has not constituted specific legal framework for regulating the establishment and management of biobanks. The forthcoming special legislation is under preparation in consultation with national and international experts.<sup>3</sup> Due to the fact that Poland has not established any specific legislation concerning biobanks, the relevant legal regulation consist of generally applied provisions of legal instruments such as legislation in relation to data protection as well as certain pieces of laws concerning transplantation and its related domains. Nevertheless Poland has already transposed the relevant European Directives in the respective legal

<sup>1</sup> In an non-official translation the word “pobierać” was translated as “recovery” but it reflects the notion of collection, or harvesting.

<sup>2</sup> Unofficial translation from Polish.

<sup>3</sup> See also point 9 on Public Debates and recent developments.

domain into the national law. The area that is most comprehensively covered by national legislation is transplantation.<sup>4</sup>

Transplantation standards for the quality and safety of tissues and cells throughout the transplantation process are set in the national legislation via the Act on the procurement, storage and transplantation of cells, tissues and organs adopted on 1 July 2005 (Transplantation Act 2005).<sup>5</sup> Concerning the Polish legislation on transplantation, several legal regulations and ordinances also have to be mentioned, such as the Order of 14 June 1996 of the Minister of Health and Social Welfare establishing the Centre for Transplant Organization

and Coordination,<sup>6</sup> Ordinance of 1 October 1996 of the Minister of Health and Social Welfare on the Central Register of Notified Cell, Tissue, and Organ Removal Refusals, and on the modalities for recording refusals and the method of establishing the existence of a refusal in the form of a declaration,<sup>7</sup> or the Ordinance of 13 November 1996 of the Minister of Health and Social Welfare on the modalities and conditions governing the establishment of national and regional banks of cells and tissues intended for transplantation, and on the functions of such banks<sup>8</sup> as well as the Law of 26 October 1995 on the removal and transplantation of cells, tissues, and organs.<sup>9</sup>

<sup>4</sup> Directive 2006/17/EC and Directive 2006/86/EC both are implementing Directive 2004/23/EC as regards traceability requirements, notification of serious adverse reactions and events and certain technical requirements for the coding, processing, preservation, storage and distribution of human tissues and cells; Directive 2005/62/EC as regards Community standards and specifications relating to a quality system for blood establishments; Directive 2005/61/EC implementing Directive 2002/98/EC as regards traceability requirements and notification of serious adverse reactions and events; Directive 2004/33/EC as regards certain technical requirements for blood and blood components; Directive 2004/23/EC on setting standards of quality and safety for the donation, procurement, testing, processing, storage and distribution of human tissues and cells.

<sup>5</sup> Act on the procurement, storage and transplantation of cells, tissues and organs adopted on 1 July 2005. (Cells and Tissues Act or historically: Transplantation Act 2005) (Dz. U. 2005 Nr 169, poz. 1411) In original language: Ustawa o pobieraniu, przechowywaniu i przeszczepianiu komórek, tkanek i narządów. Available at: <http://www.poltransplant.org.pl/contents4.html> Entered into force on 1 January 2006. Unofficial English translation is available at: [http://www.poltransplant.pl/Download/transplantation\\_act.pdf](http://www.poltransplant.pl/Download/transplantation_act.pdf)

<sup>6</sup> Order of 14 June 1996 of the Minister of Health and Social Welfare establishing the Centre for Transplant Organization and Coordination, Poltransplant. Dziennik Urzędowy Ministerstwa Zdrowia i Opieki Społecznej, 23 July 1996, No. 8, pp. 107- 108, Text No. 22

<sup>7</sup> Ordinance of 1 October 1996 of the Minister of Health and Social Welfare on the Central Register of Notified Cell, Tissue, and Organ Removal Refusals, and on the modalities for recording refusals and the method of establishing the existence of a refusal in the form of a declaration. (Dziennik Ustaw Rzeczypospolitej Polskiej, 23 October 1996, No. 124, pp. 2626-2628, Text No. 588)

<sup>8</sup> Ordinance of 13 November 1996 of the Minister of Health and Social Welfare on the modalities and conditions governing the establishment of national and regional banks of cells and tissues intended for transplantation, and on the functions of such banks. (Dziennik Ustaw Rzeczypospolitej Polskiej, 11 December 1996, No. 144, pp. 2955-2956, Text No. 668)

<sup>9</sup> Law of 26 October 1995 on the removal and transplantation of cells, tissues, and organs. Dziennik Ustaw Rzeczypospolitej Polskiej, 6 December 1995, No. 138, pp. 2008-3012, Text No. 682.

In addition to the Transplantation Act and its related regulations the Public Blood Service Act 1997 (Dz. U. 1997 Nr 106 poz. 681)<sup>10</sup> is also relevant in the respective legal domain. Chapter 6 of the Public Blood Service Act deals with the National Centre for Blood Services which is responsible for blood storage in Poland.

One of the most important legislation in the absence of specific legislation relevant for the operation of biobanks is Act on the Protection of Personal Data of 1997 (hereinafter: Personal Data Protection Act 1997 (Dz. U. 1997 Nr 133 poz. 883 with later amendments).<sup>11</sup> Pursuant to Article 46 of the Data Protection Act the Minister of Internal Affairs and Administration adopted the Regulation of April 29 2004 as regards specimen for a notification of a data filing system to registration by the Inspector General for Personal Data Protection.<sup>12</sup>

In addition to the above the Act on the Professions of Physicians and Dentists of 1996 ("Medical Profession Act")

(Dz.U. 1997 Nr 28 poz. 152)<sup>13</sup> is also relevant to the examined legal domain. While Chapter 4 of the Medical Profession Act regulates the main provisions on participation in medical experiments, Articles 30-32 contain further provisions on the acquisition and requirements of an informed consent to medical intervention. The professional rules relating to medical research, which are included in the Medical Profession Act are also in compliance with the norms set by the World Medical Association Declaration of Helsinki.

The Medical Profession Act also regulates the obligation of professional privacy subjected to medical professionals (Article 40). Given the sensitivity of the genetic data collected for tissue banks or biobanks, confidentiality and legally established professional secrecy is of great importance.

The Patient Rights and Patient Rights Ombudsman Act of 2008<sup>14</sup> regulates the individual's rights to information, privacy and confidentiality, access to medical documentation. In case of cul-

<sup>10</sup> Public Blood Service Act 1997 (Dz. U. 1997 Nr 106 poz. 681) Adopted on 22 August 1997. Entered into force on 1 January 1999. In original language: Ustawa o publicznej służbie krwi. Available at: <http://www.abc.com.pl/serwis/du/1997/0681.htm>

<sup>11</sup> Act on the Protection of Personal Data 1997 (or: Personal Data Protection Act 1997) (Dz. U. 1997 Nr 133 poz. 883 with later amendments). Adopted on 29 August 1997, entry into force on 30 April 1998. In original language: Ustawa o ochronie danych osobowych, Available at: <http://isip.sejm.gov.pl/servlet/Search?todo=open&id=WDU19971330883>

<sup>12</sup> Regulation of April 29, 2004 by the Minister of Internal Affairs and Administration as regards specimen for a notification of a data filing system to registration by the Inspector General for Personal Data Protection, Journal of Laws of 2004, No. 100, item 1025.

<sup>13</sup> Act on the Professions of Physicians and Dentists 1996 ("Medical Profession Act") (Dz.U. 1997 Nr 28 poz. 152) An excerpt is available in English language at: <http://www.federa.org.pl/?page=news&newsid=630&lang=2> In original language: Ustawa o zawodach lekarza i lekarza dentysty. Adopted on 5 December 1996, entered into force on 27 September 1997. Available in original language at: <http://www.mp.pl/prawo/index.php?aid=40167>

<sup>14</sup> Act on Patient Rights and Patient Rights Ombudsman 2009 (Dz. U. 2009 Nr 52 poz. 417) In original language Ustawa o prawach pacjenta i Rzeczniku Praw Pacjenta. Adopted on 6 November 2008, entered into force on 21<sup>st</sup> May 2009. Available at: [www.orka.sejm.gov.pl/proc6.nsf/ustawy/283\\_u.htm](http://www.orka.sejm.gov.pl/proc6.nsf/ustawy/283_u.htm)

pable breach of patients' rights, he or she can demand monetary compensation (Article 4).

In addition to the aforementioned legislative framework, the Code of Medical Ethics<sup>15</sup> that was passed at the 2nd General Medical Assembly in 1991 is also worth mentioning. It was significantly amended at the 3rd General Medical Assembly in 1993 and at the 7th General Medical Assembly in 2003 in order to update the Code according to the current developments, e.g. new provisions on the relations between the physician and the medical industry were introduced.

In cases regarding doctors, it would either be the Medical Court of the local medical chambers or the Supreme Medical Court of the main Medical Chamber who take action and proceed against those who failed to comply with the respective regulations. The courts would consider the doctors' adherence to the principles of the Code of Medical Ethics. They have the power to award various penalties and/or revoke a doctor's license for serious breaches of the Code.

The Medical Code of Ethics is not positive source of law. Nevertheless, the Act on Physicians Chambers<sup>16</sup> requires physicians to obey the Code (Article 15). It is worth mentioning that medical conduct that is in breach of the Code

can be deemed as contrary to the principles of conduct in community and give rise to civil actions against physicians.<sup>17</sup> The Polish Supreme Court stated in its verdict on 1 December 2006 that breach of deontological norms may be a basis for tort liability.<sup>18</sup> The Polish Constitutional Tribunal also gave various opinions on Medical Code of Ethics.<sup>19</sup>

Genetic testing in Poland is mainly regulated by the legal framework that applies to health services as a whole. Consequently, the regulations on patient rights are *mutatis mutandis* applicable as rights of users of genetic services.

Article 29 of the Code of Medical Ethics relates to the protection of genetics information. According to this Article, the physician and medical staff shall grant the confidentiality of genetics data. Article 38 Section (3) obliges the physician to give information to pregnant women about the possibility of genetic prenatal examination and give information about the possible risk connected with such a form of diagnose. The problem of human genetics is also regulated in the recently added chapter IIb of the Code. According to its provisions, genetic testing can only be used for medical purposes. The patient shall have access to a special genetic consultation. Any intervention on the human genome has

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<sup>15</sup> Medical Code of Ethics adopted by 2nd General Medical Assembly in 1991 Available at: [http://www.nil.org.pl/xml/nil/wladze/nil\\_eng/med\\_code](http://www.nil.org.pl/xml/nil/wladze/nil_eng/med_code) In original language: Kodeks Etyki Lekarskiej. Available at: [http://www.nil.org.pl/xml/nil/wladze/str\\_zl/zjazd7/ke](http://www.nil.org.pl/xml/nil/wladze/str_zl/zjazd7/ke)

<sup>16</sup> Act on the Physicians Chambers 1989 (Dz.U. Nr 30 poz. 58) In original language: Ustawa o izbach lekarskich. Adopted on 17<sup>th</sup> May 1989, entered into force on 26<sup>th</sup> May 1989. Available at: <http://www.portalmed.pl/xml/prawo/medycyna/medycyna/podst/izby>

<sup>17</sup> See M. Śliwka, *Prawa pacjenta w prawie polskim na tle prawnoporównawczym*, Toruń 2008.

<sup>18</sup> I CSK 315/06, OSNC 2007 r., nr 11, poz. 169, *Prawo Bankowe* 2007 r., nr 11.

<sup>19</sup> See verdict given on: 7<sup>th</sup> October 1992, U 1/92, OTK 1992 r., nr 2, poz. 38 and 17<sup>th</sup> March 1993, W 116/92, OTK 1993 r. nr 1, poz. 16.

to have therapeutic or prophylactic aim. The intervention aiming at cause the hereditary changes in human genome is forbidden. There is no specific provision prohibiting discrimination on the basis of genetic heritage.

### Protection of Privacy and Data Protection in Poland

According to Article 47 of Polish Constitution:<sup>20</sup>

*“Everyone shall have the right to legal protection of his private and family life, of his honor and good reputation and to make decisions about his personal life.”*

According to Stefanicki this covers some constant values and rights (i.e. the right to establish the zone free from external curiosity and other interventions, the right to be left alone, informational autonomy).<sup>21</sup> Rudnicki perceives this right as competency to form our own life.<sup>22</sup>

Article 51 states the following:

“1. No one may be obliged, except on the basis of statute, to disclose information concerning his [or her] person.

2. Public authorities shall not acquire, collect nor make accessible information on citizens other than that which is necessary in a democratic state ruled by law.

3. Everyone shall have a right of access to official documents and data collections concerning him- [or her]self. Limitations upon such rights may be established by statute.

4. Everyone shall have the right to demand the correction or deletion of untrue or incomplete information, or information acquired by means contrary to statute.

5. Principles and procedures for collection of and access to information shall be specified by statute.”

Article 76 also protects privacy by stating that public authorities shall protect consumers, customers, hirers or lessees against activities threatening their health, privacy and safety, as well as against dishonest market practices. The scope of such protection shall be specified by statute.

As Atina Krajewska and Marcin Sliwka emphasized in their work in the Privileged Project there is no clear concept of privacy in Poland. Usually it is associated with informational privacy. Authors use terms ‘privacy’ or ‘private sphere’ to protect most sensitive information on health status, sexual life or family life,<sup>23</sup> religion and political beliefs,<sup>24</sup> etc. Sometimes it is stressed that the right to intimacy<sup>25</sup> is a part of the broader right to priva-

<sup>20</sup> The Constitution of the Republic of Poland of 2nd April, 1997. As published in Dziennik Ustaw No. 78, item 483 Adopted by National Assembly on 2 April 1997. Confirmed by Referendum in Oct 1997, Available at: <http://www.sejm.gov.pl/prawo/konst/angielski/kon1.htm> In original language: Konstytucja Rzeczypospolitej Polskiej. Available at: <http://www.sejm.gov.pl/prawo/konst/polski/kon1.htm>

<sup>21</sup> R. Stefanicki, Cywilnoprawna ochrona prywatności osób podejmujących działalność publiczną, St.Prawn. 2004/1/25.

<sup>22</sup> S. Rudnicki, Głosa do wyroku SN z dnia 21 listopada 2003 r., V CK 16/03, M.Prawn. 2004/10/475.

<sup>23</sup> K.W. Kubiński, Ochrona życia prywatnego człowieka, RPEiS 1993/1/61

<sup>24</sup> A. Sakowicz, Ingerencja w prywatność musi być usprawiedliwiona, Rzeczposp. 2006/8/29.

<sup>25</sup> J. Sieńczyło-Chlabicz, Prawo do ochrony sfery intymności jednostki, PiP 2004/11/34.

cy.<sup>26</sup> For example, the term “privacy” was used to describe the situation of employees being monitored in work environment by their employer.<sup>27</sup>

In Poland, the right to private life is considered to be a personal interest, a value accepted both by society and the legal system. Personal interests (including privacy) are protected both by the Polish Constitution and the Polish Civil Code. Personal interests (including broad concept of privacy<sup>28</sup>) are protected by the Polish Civil Code. Article 23 of the Civil Code lists exemplary personal interests such as: health, freedom, dignity, freedom of conscience, surname or pseudonym, image, secrecy of correspondence, inviolability of home, scientific, artistic, inventor’s and rationalizing achievements. Despite the fact that privacy is not listed in the above mentioned Article, it is generally accepted as a kind of personal interest. A person harmed by negligent infringement of personal rights (including the right to privacy) may claim compensation for moral damage in an action based on Article 448 of Civil Code.

In terms of definitions within the Polish Act on the Protection of Personal Data of 1996 (also: Personal Data Protection Act, PDPa 1996) the implementation of the EU Directive took a form of a literary translation. The term

personal data has been defined in Article 6 Section (1) of the Act as “data concerning an identified or identifiable natural person”. An identifiable person is one, whose identity can be determined directly or indirectly, in particular either through an identification number or through one or a more circumstances referring to his or her physical, physiological, mental, economic cultural or social characteristics. The person is not considered identifiable, if obtaining this information would require excessive costs, time or actions. The term excessive should be understood as ‘unreasonable’ or ‘disproportional’.<sup>29</sup>

The Data Protection Act regulates the processing of personal data only and does not refer to the carrier of the information (e.g. floppy disc or chemical substance). Therefore, the issue of biological samples falling under its scope is debatable. This debate has already taken place in Germany,<sup>30</sup> but it has not been echoed in Poland (neither in case-law, nor in literature<sup>31</sup>). There are two possible interpretations stemming on the one hand from the ‘*sui generis*’ status of the DNA<sup>32</sup> and on the other hand from the definition of personal data as it stands in the Act. Our interpretation of the Act is that it covers only the data ‘extracted’ and translated into a row of letters, and later

<sup>26</sup> *Ibidem*, 34.

<sup>27</sup> T. Liszcz, *Ochrona prywatności pracownika w relacjach z pracodawcą*, M.P.Pr. 2007/1/9

<sup>28</sup> As described by AL Allen, *Genetic Privacy: Emerging Concepts and Values*, 1997/31-60.

<sup>29</sup> J. Barta, R. Markiewicz, *Ochrona danych osobowych. Komentarz*, Kraków: 2001, 505.

<sup>30</sup> C.Grand/K. Atia-Off, *Genmedizin und Datenschutz*, w: S.F. Winter/ H. Fenger/ H-L. Schreiber (red.), *Genmedizin und Recht*, Monachium 2001, p. 538-540 and D.Brückl, *Rechtsfragen zur Verwendung von genetischen Informationen über den Menschen. Ein Beitrag zur Steuerung der Verwendung von Wissen*, Berlin 2001, p. 118

<sup>31</sup> The discussion has been introduced to the Polish literature by: A. Krajewska, *Genetic Information and the Scope of Personal Autonomy in the European Legal Space*, Wrocław 2008.

<sup>32</sup> *Moore v Regents of the University of California*, 793 P 2d 479 (1990), 1759-1764.

analyzed. The mere fact of holding a biological sample cannot mean ‘processing of data’.

In Article 5 the Polish PDPA 1996 states that its provisions constitute *lex generalis* in relation to other statutes, as long as they introduce higher protection of personal data. Therefore, the use of biological material in Poland is regulated by fragmented pieces of legislation: to some extent by the Polish Transplantation Act 2005, Laboratory Diagnosis Act 2001.<sup>33</sup> Medical Devices Act 2004, the Act on the Professions of Physicians and Dentists 1996, and the general provisions of the Civil Code. In case of biobanks all these statutes apply simultaneously depending of the purpose and context of the use of biological samples and the processing of data derived from them. Such an interpretation seems to be supported by the formulation of the Transplantation Act 2005, which addresses the issues concerning the processing of personal data separately from the collection and preservation of cells, tissues and organs.

Article 49 Section (1) of the PDPA also sets forth that if a person, who processes personal data in a data filing system where such processing is forbidden or where he or she is not authorized to carry out such processing, shall be liable to a fine, a partial restriction of freedom or a prison sentence of up to two years. Furthermore Section (2) sets out more strict regulations in case the offence mentioned in Article 49 Section (1) relates to informa-

tion on racial or ethnic origin, political opinions, religious or philosophical beliefs, religious, party or trade-union membership, health records, genetic code, addictions or sexual life, the person who processes the data shall be liable to a fine, a partial restriction of freedom or a prison sentence of up to three years.

It is worth mentioning that conduct of most of the Polish Ethics Committees in Poland, in case of research on samples obtained for primary research purposes is based upon two statutes: the Data Protection Act and the Act on the Professions of Physicians and Dentists. The Polish Ethics Committees tend to apply the Data Protection Act when it comes to processing data (understood as row of letters, for example in the research results). When it comes to obtaining and conducting research on biological material of human origin it is often perceived as medical experiment that falls within the scope of Chapter 4 of Act on the Professions of Physicians and Dentists (Medical Experiment). In such case the participant’s consent and Ethics Committee approval is necessary.

### 3. ESTABLISHMENT AND MANAGEMENT OF BIOBANKS

Chapter 6 of the Transplantation Act explicitly deals with tissue and cell banks, according to which Articles 25 and 26 sets forth that cell and tissue

<sup>33</sup> Laboratory Diagnosis Act of 27 July 2001 (Dz. U. z dnia 18 września 2001 r.), In original language: Ustawa o diagnostyce laboratoryjnej z 27 lipca 2001 r. Available at: <http://www.abc.com.pl/serwis/du/2001/1083.htm>

banks shall be established upon the permission of the Minister responsible for health and with the aim of gathering, processing, sterilizing, storing and distributing tissues and cells appropriated for transplantation. The application for permission to establish a cell and tissue bank in Poland shall be submitted via the National Centre for Tissue and Cell Banking<sup>34</sup> and the permission is subjected to the prior opinion of the National Transplantation Council [Article 26, Section (3), (4)]. In addition to the above Section (4) also sets forth that the permission shall be given for five years.

The Cells and Tissue Act does not differentiate between biobanks for research and medical purposes which seems to indicate that the opinion is given in case of any biobank. However, it is not clear whether it applies also to biobanks for research purposes. Systematic interpretation suggests that the Transplantation Act applies to biobanks established for transplantation purposes. In such case one might wonder what can be regarded as an appropriate legislation for governing, establishing and managing biobanks. It seems that it is possible that establishing biobanks and conducting research on obtained biological materials fall within the category of research experiment that is governed by Article 21.3 of the Act on the Professions of Physicians and Dentists. It is defined as experiment conducted mainly for extending the scope of medical knowledge, not necessarily serving for the participant treatment purposes. If the re-

search on human tissue falls within this category, than the Physician and Dentist Act should be applicable instead of the Transplantation Act. This would mean that in practice the establishment of the biobanks for research relies on decisions made by local Research Ethics Committees.

#### 4. PECUNIARY ASPECTS

Article 3 of the Transplantation Act provides the relevant provisions on the pecuniary aspects in relation to the transplantation of cells, tissues or organs taken from donors. Section 1 sets forth that "It is not allowed to demand or accept payments or other financial benefit for cells, tissues and organs taken from donors." The Transplantation Act seems to treat biological samples as material objects that are outside of trade (*res extra commercium*). In line with civil law doctrine, excluding any sort of pecuniary reward for donating human tissue is quite a common approach as it is agreed that they cannot be subject to civil contract.

Nevertheless, according to Section (2) of Article 3, the repayment of costs of recovery, storage, processing, sterilization, distribution and transplantation of cells, tissues or organs taken from donors shall not be deemed as a payment or financial benefit within the meaning of the aforementioned provision. Section (3) of Article 3 provides the notion of the above mentioned costs, according to which it means

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<sup>34</sup> Krajowe Centrum Bankowania Tkanek i Komórek. Further information is available in Polish at: <http://www.kcbtik.pl/?Strona%0Ag%B3%26oacute%3Bwna>

"[...]a recovery of cells, tissues or organs from a donor; a hospitalization of a potentially living donor; an issuance of medical opinions; a recovery procedure; laboratory tests performed before and after the recovery; a cell culture for transplantation; a transport from or to the medical care institution where the transplantation has to be done; a storage, processing and sterilization."

The repayment of costs shall be done by the medical care institution, which has been supplied with cells, tissues or organs for transplantation. The Minister responsible for health matters shall by means of a decree regulate the manner of setting the costs of activities related to recovery, storage, processing, sterilization and distribution of cells, tissues and organs and also the manner of repaying these costs, including costs referred to in Section (3) of Article 3 and procedures in relation thereof.

## 5. CONSENT

In relation to constitutional provisions on personal freedoms and privacy, Article 39 of Polish Constitution sets forth that

"No one shall be subjected to scientific experimentation, including medical experimentation, without his [or her] voluntary consent."

In addition to the aforementioned provision, Article 7 of the Data Protection Act sets out the definition of a data subject's consent, according to which it shall mean a declaration of will by which the data subject signifies his or her agreement to the processing of his or her personal data, however the con-

sent cannot be used for other purposes than the one explicitly mentioned in the first place.

Article 23 of the Data Protection Act sets out the basic legal regulations in relation to the data subject's consent to the processing of his or her personal data, according to which it is solely appropriated on the condition that the data subject has given his or her consent, unless the processing consists in erasure of personal data. The processing of personal data without the data subject's consent is forbidden, however Article 23 also sets forth several exemptions to that rule. The personal data protection is permitted even without the consent of the data subject if the (1) processing is necessary for the purpose of exercise of rights and duties resulting from a legal provision; (2) processing is necessary for the performance of a contract to which the data subject is a party or in order to take steps at the request of the data subject prior to entering into a contract; (3) processing is necessary for the performance of tasks provided for by law and carried out in the public interest; (4) processing is necessary for the purpose of the legitimate interests pursued by the data controllers or data recipients, provided that the processing does not violate the rights and freedoms of the data subject.

Special rules are provided for the processing of sensitive data, which is defined in Article 27 of the Act as:

"data revealing racial or ethnic origin, political opinions, religious or philosophical beliefs, religious, party or trade-union membership, as well as the processing of data concerning health, genetic code, addictions or sex life and data relating to convictions, decisions

on penalty, fines and other decisions issued in court or administrative proceedings shall be prohibited.”

The processing of the aforementioned sensitive personal data is permitted only in certain cases specified in Article 27 Section (2) of the Act, e.g. if the (1) data subject has given his or her written consent, unless the processing consists in the erasure of personal data; (2) the specific provisions of an other statute permits the data processing without the data subject’s consent and also provides for adequate safeguards; (3) processing is necessary to protect the vital interests of the data subject or of another person where the data subject is physically or legally incapable of giving his or her consent until his or her guardian has been appointed; (4) processing relates to the data necessary to pursue a legal claim; (5) processing is necessary for the purposes of carrying out the obligations of the data controller with regard to employing his or her employees and other persons, and the scope of processing is provided by the law; (6) processing is required for the purposes of preventive medicine, the provision of care or treatment, where the data are processed by a health professional who is involved in treatment, other health care services, or the management of health care services and this data processing also has appropriate safeguards; (7) the processing relates

to those data which were made publicly available by the data subject; (8) it is necessary to conduct scientific researches including preparations of a thesis required for graduating from university or receiving a degree; any results of scientific researches shall not be published in a way which allows identifying data subjects; (9) data processing is conducted by a party to exercise the rights and duties based on decisions issued in court or administrative proceedings. It also has to be mentioned that the Polish Supreme Court gave numerous interpretations on patient’s rights (especially the right to information and consent).<sup>35</sup>

As argued above it is possible to state that processing data (understood as row of letters) is something different to conducting research on biological materials of human origin. If this is true than different laws apply when discussing consent for participation in research than in case of consent for data processing. Article 24.1 of the Physicians and Dentist Act sets forth that a person to be subjected to a medical experiment shall be informed beforehand on the purposes, methods, and conditions under which the experiment shall be run, and the expected therapeutic or cognitive benefits, the risk and a possibility of withdrawal from participation in the experiment at any stage thereof. According to Article 25 of the same act, it is possible to conduct me-

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<sup>35</sup> The following decisions of the Polish Supreme Court does not explicitly concern biobanking but can be applicable : 1977-3-17, I CR 70/77, OSP 1977 r., nr 4, poz. 76; 1980-9-5, II CR 280/80, OSPiKA 1981 r., nr 10, poz. 170, 2001-1-10, III CKN 1008/98, Lex nr 51352; 2006-04-11, I CSK 191/05, OSNC 2007 r., nr 1, poz. 18; 1989-02-17, OSNKW 1989, nr 5-6, poz. 42; 2004-12-17, II CK 303/04, OSP 2005 r., nr 11, poz. 131; 1998-03-10, I CKN 571/97, OSNC 1998 r., nr 10, poz.170; 1983-06-14, IV CR 150/83, Lex nr 8545; 1960-02-07, IV CR 991/59, OSPiKA 1970r., nr 11, poz.224; 1972-08-28, II CR 296/72, OSNC 1973 r., nr 5, poz.86.

dical experiment after obtaining the written consent of the participant. If the written consent cannot be obtained, it is possible to give consent in presence of at least two witnesses and notification in medical documentation. The cited provision of the Physicians and Dentist Act is as follows:

“The running of a medical experiment shall require a written consent from its prospective participant who is to undergo the examination and who has been informed beforehand in the manner set forth in Article 24.1. If the granting of a written consent is not possible, a consent granted orally in the presence of two witnesses shall be deemed to be an equivalent thereof. A note should be taken of a consent so granted in the medical documentation.”

### 5.1. Consent of minors, people with limited capacity

Article 5 of the Transplantation Act provides the legal basis for the opposition of minors or people with limited capacity and sets forth that the legal representative thereof is entitled to take an objection for the interest of such individuals. In line with the above mentioned regulations if the person is a minor a substitute consent is required from his or her legal representative, guardian-in-fact or a guardianship court. When the person is 16 years old, a double consent is needed and besides the substitute consent of his or her legal representative, the minor above 16 years old shall also state his or her objection. Similar regulations

apply in case of research regulated within the Physician and Dentist Act (Article 25.2). In addition to the above, the Physicians and Dentist Act also provides in Article 25.3-4 that in the case of a wholly incapacitated person, a consent for the said person’s participation in medical experiment shall be granted in writing by his or her statutory representative. If the said person is capable of expressing his or her informed opinion on his or her participation in the medical experiment, his or her written consent shall also be required. In the case where the statutory representative denies his or her consent to the aforementioned person’s participation in the medicinal experiment or it is impossible to obtain such consent, one may request that the probate court competent with respect to the seat of the entity running the experiment grant their consent.

### 5.2 Consent of diseased persons

The PDPA 1996 regulates the use of data concerning a natural person. “Everybody has a right to the protection of personal data”. Since the Act does not provide a definition of a natural person, the interpretation will stem from the formulation present in the Civil Code. According to Article 2 of the Polish Civil Code<sup>36</sup> the legal personality begins at the moment of a person’s birth. The only exceptions relates to the ‘*nasciturus* rule’ (an unborn child, if subsequently born alive, is considered as already in existence whenever it is to its own advantage). Legal personality

<sup>36</sup> Ustawa Kodeks Cywilny (Polish Civil Code), 23 April 1964, Dz.U.64.16.93

ends with the person's death. Therefore, the PDPA 1996 will not apply to deceased persons. The deceased person is afforded some level of protection through the Civil Code, which gives the person's family members the possibility to protect the person's good name against defamation. The rights rest with the person's family members.

However, the existing Transplantation Act 2005 (which will most probably be soon complemented or replaced by two acts concerning biobanks and embryos *in vitro*<sup>37</sup>) contains provision on the extraction of tissues, cells and organs from the deceased persons (which is typical for a piece of legislation concerning transplantation). The Act operates on the presumption that the deceased person has given consent. According to Article 4 "it is allowed to recover cells, tissues and organs from human cadavers for diagnostic, therapeutic, research or didactic purposes. It is allowed to recover cells, tissues or organs also during postmortem examinations that are being performed on the basis of separate regulations." According to Article 4 Section (1), "if a deceased person did not express objection, when alive, it is allowed to recover cells, tissues, or organs from such person's human cadaver for transplantation purposes." The data of a deceased person are stored for further 5 years and then are destroyed.

Considering the above mentioned objection to such intervention, Article 7 sets out that the objection shall be sub-

mitted in three forms. The Central Objection Register is managed by the "Poltransplant", the Organization and Co-ordination Center for Transplantation Issues<sup>38</sup> and the registration of such objections to recover cells, tissues and organs from one's own human body may be submitted to this Register. The objection as set out in Article 7 may also be declared in a written and signed statement as well as with an oral statement made in the presence of at least two witnesses and confirmed by these witnesses in writing.

## 6. ACCESS TO DATA OR SAMPLES, AND ANONYMITY

According to Chapter 4 of the Data Protection Act everyone has the right to control the processing of his or her personal data contained in data filing systems, and has the right to be informed whether such databases exist and who administers them. Therefore the data subject is entitled to obtain extensive information on the data controller's identity, the address of its seat and its full name, and in case the controller is a natural person to obtain his or her full name and address. Furthermore the data subject is also entitled to obtain information on the purpose, scope, and the means of the data processing, as well as to obtain information on whether his or her personal data are being processed in a coded form. The queries of the data subject should be answered within thirty days.

<sup>37</sup> In October 2008 the Polish *ad hoc* Bioethics Committee is supposed to present its recommendations with regard to the legislation which should accompany the implementation of the Biomedical Convention.

<sup>38</sup> <http://www.poltransplant.org.pl/>

Upon finding out that data is incorrect, inaccurate, outdated or collected in a way that constitutes a violation of the Data Protection Act, citizens have the right to request that the data be corrected, filled in or withheld from processing.

The security transfer of personal data to other countries is covered by Articles 47-48 of the Data Protection Act. In accordance with Directive 95/46/EC, Article 47 sets out the general prohibition on the transfer of personal data to a third country, if the country of destination does not provide at least the same level of personal data protection in its territory as that in force on the territory of the Republic of Poland.

The Act does not include a definition of 'anonymised' data, although it mentions the anonymisation procedure in Article 2 Section (3). This provision excludes 'anonymised data' from the scope of the Act. However, there is one exception to this general rule. Chapter 5 of the Act, regulating the safeguarding of data collections, applies to such (anonymised) data. Our understanding of the formulation of this provision is that it concerns data, which can not be linked to an identifiable person (either because it is impossible or because it would involve 'excessive costs, time, actions'). Consequently, 'anonymised' and 'reference' collections fall outside the scope of the Polish PDPA 1996.

## 7. STORAGE

The data controller is obliged to notify the Chief Inspector for Data Protection on establishing a data filing system as set out in Article 40 of the Data Protection Act. Article 42 also provides

that the Chief Inspector for Data Protection shall keep a national, public register of personal data filing systems. It is also worth mentioning that the Data Protection Act also sets forth several exemptions to the above mentioned requirement. The obligation to register data filing systems shall not apply to data that e.g. (1) constitutes a state secret in the interest of state defence or security, protection of human life and health, property, security, or public order; (2) were collected as a result of inquiry procedures held by officers of the bodies authorized to conduct such inquiries, (3) are processed by relevant bodies for the purpose of court proceedings and on the basis of the provisions on the National Criminal Register. Registration details must include the name and address of the data controller, the scope and purpose of the data processing, methods of collection and disclosure, and the security measures. The specimen of a notification of the data filing system to registration by the Inspector General are constituted in the Appendix to the Regulation of April 29, 2004 as regards specimen for a notification of a data filing system to registration by the Inspector General for Personal Data Protection. The Chief Inspector for Data Protection has the right to access data, check data transfer and security systems, and determine whether the information gathered is appropriate for the purpose that it is supposed to serve.

## 8. SUPERVISION

The National Centre for Tissue and Cell Banking is a body that keeps the licensing record for the establishment of a

cell and tissue bank, furthermore according to Article 27 of the Transplantation Act it has to be notified of all changes. In addition to the above the Ministry of Health and Social Welfare is responsible for the supervision of the cells and tissue banks as well as the operation of biobanks. In relation to the management of such genetic databases the establishment and operation of the ethical committees (Research Ethical Committees, RECs) is also important for the relevant legal domain.

### 8.1. Ethical Committees

The first research ethics committees were established in Poland in the 1980s due to increasing cooperation with Western institutions and ethical review was necessary if researchers wanted to publish results or indeed collaborate in international projects.

The research ethical committees obtained legal recognition under the Medical Profession Act of 1996. There was more specific legislation in a Decree by the Ministry of Health 1999,<sup>39</sup> which sets the principles of the establishment, funding and operation of RECs. Further relevant legislation has to be mentioned in relation to clinical trials,

firstly the Order of the Minister of Health in the matter of Central Register of Clinical Trials<sup>40</sup> and Order of the Minister of Health concerning detailed requirements of Good Clinical Practice which was the most important legislation that transposed Directive 2001/20/EC on the approximation of the laws, regulations and administrative provisions of the Member States relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use.<sup>41</sup>

Proceeding a clinical trial is subjected to the approval of a local REC, a permit from the Ministry of Health and be registered with the Central Register of Clinical Trials, maintained by the Ministry of Health.

Since Poland has no Central Ethics Committee as other EU Member States, the work of local RECs is significant in the relation to the ethical review of research projects. Three types of ethics committees operate in Poland that promote good conduct and good clinical trial practice: (1) RECs of Medical Universities, (2) RECs of Regional Chambers of Physicians and Dentists and (3) RECs of (non-university) Medical or Scientific Institutes<sup>42</sup>.

In 2007 the Polish Supreme Administrative Court delivered an opinion

<sup>39</sup> Regulations of the Minister of Health (May 11, 1999 Order of the Minister of Health and Social Welfare in the matter how to establish, create finance for and the mode of action of Bioethics Committees. Legislation Journal of the Republic of Poland (1999) 47: Pos. 480)

<sup>40</sup> Order of the Minister of Health in the matter of Central Register of Clinical Trials, Legislation Journal of the Republic of Poland (2002) 209: Pos. 1783, November 29, 2002

<sup>41</sup> Order of the Minister of Health concerning detailed requirements of Good Clinical Practice; Ministry of Health Act Nr.221 poz.1864. Legislation Journal of the Republic of Poland (2002) 221: Pos. 1864, December 10, 2002

<sup>42</sup> Further information and figure are available at:

<http://www.pubmedcentral.nih.gov/articlerender.fcgi?artid=2423453&rendertype=figure&id=F1> (Danuta Ligocka: Bioethical committees and data protection issues in Poland. *Enviro Health*. 2008; 7(Suppl 1): S4. Published online 2008 June 5. 2008 Ligocka; licensee BioMed Central Ltd. <http://www.pubmedcentral.nih.gov/articlerender.fcgi?artid=2423453>)

on the status of the decisions made by ethics committees.<sup>43</sup> An opinion of the ethics committee on medical experiment protocol is an administrative decision and therefore can be subject to appeal to the administrative court. According to the EFGCP Report on Poland in relation to the ethical review of protocols for clinical research projects<sup>44</sup> there are 54 Regional Bioethics Committees and one Appeal Bioethics Committee at the Ministry of Health. The 54 Regional Committees comprise 13 bodies appointed by the Medical Universities, 18 appointed by the Medical or Scientific Institutes, 23 appointed by the Regional Chambers of Physicians and Dentists.

There are certain local ethical committees that are operated at medical schools or universities which conduct medical research; medical research and development institutes are entitled to submit application to them.

Other local RECs function in the framework of Regional Medical Chambers to which doctors or medical professionals who conduct clinical trials are allowed to submit an application. In addition to the above researchers at non-affiliated institutes are also entitled to request the opinion of research ethical committees at the Regional Medical Chambers. The Regional Chambers are the regulatory bodies for doctors and dentists in Poland.

The third type of local RECs are situated at medical research and development institutes to which the researchers at the institute are entitled to submit an application.

There are no legally defined penalties for failure to follow review of the research ethic committees, although it is assumed that medical professionals are legally and professionally responsible for their research. Appeals against REC decisions are handled by the Bioethical Committee of Appeals which is established by the Ministry of Health in conjunction with the Supreme Medical Chamber.

## 9. PUBLIC DEBATE AND RECENT DEVELOPMENTS

In 'Social values, science and Technology' (Special Eurobarometer 225/Wave 63.1) respondents were asked the following: "How important do you think protecting information about our private life from misuse and exploitation will be for our society in ten years time?"

In all countries, a majority believes that protecting such information is very important. Similarly in Poland, 67 % thinks it is very important and 26 % believes it is fairly important.

According to current developments several news has been published on Poland's intention to launch its first

<sup>43</sup> II OSK 1112/06, Centralna Baza Orzeczeń Sądów Administracyjnych

In original language: <http://orzeczenia.nsa.gov.pl/doc/F323754791> and LEX nr 320105

<sup>44</sup> European Forum for Good Clinical Practice (EFGCP) Report on the Procedure for the Ethical Review of Protocols for Clinical Research Projects in Europe, Report on Poland, updated in 2008.

[http://www.efgcp.be/Downloads/EFGCPRReportFiles/Flow%20Chart%20Poland%20\(revised\)%2008-03-01.pdf](http://www.efgcp.be/Downloads/EFGCPRReportFiles/Flow%20Chart%20Poland%20(revised)%2008-03-01.pdf)

national biobank and related legislation on genetic molecular tests in the country.<sup>45</sup> The initiative follows the example of some other European countries where biobanks already exist in Iceland, Sweden, Great Britain, Spain and Estonia. The future Polish biobank will be coordinated by the Ministry of Science and Higher Education and the forthcoming national legislative framework on the establishment and management of biobanks has to adopt several amendments in order to be in compliance with international and European standards. Having fulfilled those, Poland will be able to join the Biobanking and Biomolecular Resources Research Infrastructure (BBMRI) created as a part of the Seventh Framework Programme (FP7) and the country will become eligible for FP7 funding to further support the proj-

ect.<sup>46</sup>The Polish – British Molecular Genetics Forum was organised by the SIN Warsaw and the Polish Ministry of Science and Higher Education<sup>47</sup> between 1-3 June 2009. The development of biobanks arises ethical, legal and social issues which allow for solutions that guarantee innovation and patient protection, therefore establishment of the regulative framework for biobanks in Poland set the context for the forum. The conference was held on “Challenges of molecular genetic testing in Poland – proposals for regulations” and preceded by meetings among scientists from the UK and Poland to explore opportunities for future collaboration.

The conference aimed to increase Ministry of Science and Higher Education’s know-how in regulating genetic services<sup>48</sup>.

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<sup>45</sup> Further information is available on the Polish biobank initiative in an interview with Prof. Michał Witt, from the International Institute of Molecular and Cell Biology in Warsaw and the Institute of Human Genetics of the Polish Academy of Sciences in Poznań, the article is available at <http://www.warsawvoice.pl/view/20626>

<sup>46</sup> <http://www.cebiotech.com/www/BiotechNews/281>

<sup>47</sup> The website of the [http://www.eng.nauka.gov.pl/ms/index.jsp?place=Menu01&news\\_cat\\_id=-1&layout=0](http://www.eng.nauka.gov.pl/ms/index.jsp?place=Menu01&news_cat_id=-1&layout=0)

<sup>48</sup> [http://www.dius.gov.uk/news\\_and\\_speeches/announcements/polish\\_british\\_molecular\\_genetic\\_forum](http://www.dius.gov.uk/news_and_speeches/announcements/polish_british_molecular_genetic_forum)

## II. FORENSIC BIOBANKS

### 1. DEFINITION OF FORENSIC BIOBANKS

Although there is no legal definition for forensic biobanks or databases in Polish legislation, according to current practice the police is entitled to collect any information of an evidential nature in the interest of criminal investigation. On the basis of Article 20 Section (1) of the Police Act the police is entitled to collect information with the aim of detecting crimes and facilitating the investigation procedure. The Central Forensic Laboratory of the General Headquarters of Police (CFLP)<sup>49</sup> is one of the main providers of forensic services in Poland. The main task of the Laboratory is to provide technical and forensic resources and casework covering most of forensic specialist areas for police and law enforcement agencies. CFLP is also responsible for the management and maintenance of forensic databases (DNA – called GENOM, Automated Fin-

gerprint Identification System – AFIS) as well as collections of exhibits.

### 2. RELEVANT LAWS

The relevant provisions of the Data Protection Act are also applicable to forensic databases and the collection of genetic information in Poland for investigating purposes. Apart of the above mentioned provisions set forth in the Data Protection Act, the Criminal Code<sup>50</sup> and the Criminal Procedural Law<sup>51</sup> are worth mentioning. In relation to the duties of the police the Police Act<sup>52</sup> has to be noted.

It is also worth mentioning the Laboratory Diagnostics Act of 27 July 2001 that regulates the access to profession of laboratory diagnostician and the legal principles of its execution.

Also Ordinance of Minister of Justice of 23 February 2005 on the examination and performance of other proceedings on accused or suspected persons<sup>53</sup> and

<sup>49</sup> Centralne Laboratorium Kryminalistyczne (CLK) Komendy Głównej Policji (KGP), further information is available at: <http://clk.policja.pl/portal/clk/698/EN.html>

<sup>50</sup> Criminal Code of 6 June 1997 (Dz.U.1997 Nr 88 poz. 553) In original language: Ustawa z dnia 6 czerwca 1997 r. Kodeks karny Część Ogólna. Available at:

<http://isap.sejm.gov.pl/DetailsServlet?id=WDU19970880553>

<sup>51</sup> Code of Criminal Procedure of 6 June 1997 (Dz.U.1997 Nr 89 poz. 555) In original language: Ustawa z dnia 6 czerwca 1997 r. Kodeks postępowania karnego. Available at:

<http://isap.sejm.gov.pl/DetailsServlet?id=WDU19970890555>

<sup>52</sup> Police Act dated April 6, 1990 (consolidated text in Dz.U. 2007 Nr 43, poz. 277). Available at:

<http://isap.sejm.gov.pl/DetailsServlet?id=WDU20070430277> Older version in English available at:

[http://www.malopolska.policja.gov.pl/eng/kgp/police\\_act.pdf](http://www.malopolska.policja.gov.pl/eng/kgp/police_act.pdf).

<sup>53</sup> Ordinance of 23 February 2005 of the Minister of Justice on the examination and performing other proceedings on accused or suspected (Dz. U. Nr 33, poz. 299) - In original language: Rozporządzenie Ministra Sprawiedliwości w sprawie poddania badaniom lub wykonywania czynności z udziałem oskarżonego oraz osoby podejrzanej.

Ordinance of the Minister of Internal Affairs and Administration of 5 September 2007 on Police data processing<sup>54</sup> are relevant in this field.

### 3. ESTABLISHMENT OF FORENSIC BIOBANKS<sup>55</sup>

The notion of establishing forensic database in Poland is based on the European Union Resolution of 9 June 1997 (97/C 193/02)<sup>56</sup> and the Council of Europe's Rec(92)1 of 10 February 1992 on the use of analysis of deoxyribonucleic acid (DNA) within the framework of the criminal justice system upon which the member states were requested to consider the possibility of creating national genetic databanks.

Several political, legal and ethical considerations have to be considered and embraced into the legislative framework of the management of such databases. The outcome of shared effort between political and legal representatives, as well as members of the police force was the amendment of the relevant provisions of the Police Act in 2001.

In the meanwhile the Polish Parliament amended the law several times, and it wasn't until 17 December 2004 when the lawmaker passed a modification as a consequence of which Article 1 stipulates that it is one of the Police's main task to run a database that includes information obtained from DNA analysis.<sup>57</sup> However some of the amendments were questioned by the Polish Ombudsman and eventually were subject to Constitutional Tribunal scrutiny. The main concern was that the Police Act didn't stipulate the conditions when gathering such data would be acceptable (Article 20 Section (2)). Also Article 20 Section (17) didn't regulate the problem of data removing in case of acquittal or proceedings termination. In its verdict given on 12 December 2005,<sup>58</sup> the Constitutional Tribunal held that Article 20 Section (2) was unconstitutional. However, in relation to Article 20 Section (17) the Tribunal didn't notice any infringement since – as the reasoning goes – under certain circumstances gathering data on acquitted persons might be appropriate given that such data is not of sensitive nature.<sup>59</sup>

<sup>54</sup> Ordinance of 5 September 2007 of the Minister of Internal Affairs and Administration on Police data processing (Dz. U. Nr 170 poz. 1203) – In original language: Rozporządzenie Ministra Spraw Wewnętrznych i Administracji w sprawie przetwarzania przez Policję informacji o osobach..

<sup>55</sup> Mieczysław Goc and Halina Dąbrowska, The Present and Future of DNA Database in Poland, Available at: [http://www.forensicscience.pl/pfs/50\\_goc.pdf](http://www.forensicscience.pl/pfs/50_goc.pdf)

<sup>56</sup> See M. Goc, J. Moszczyński, Ślady kryminalistyczne. Ujawnianie, zabezpieczanie, wykorzystanie, Warsaw 2007, p. 179.

<sup>57</sup> The amendment entered into force on 1 February 2005 – Dz. U. 2005 Nr 10, poz. 70.

<sup>58</sup> K/32/04 OTK – A 2005, nr 10, poz. 126, Dz. U. Nr 250, poz. 2116.

<sup>59</sup> In dictum the Constitutional Court stated: “Valid acquittal or decision to discontinue proceedings doesn't mean that data obtained on that individual can't contain information useful to the Police when conducting actions in respect to other person. Article 20 Section (17) of the Police Act mentions data that were obtained legally, with court approval. The possibility of preserving obtained data doesn't allow preserving so called sensitive data like those revealing racial or ethnic origin, political opinion, religious or philosophical beliefs, affiliation to religious group, political party or trade union, information on health and sexual life. Provisions under scrutiny are therefore within the legislator's competence.” (Translation by Anita Gałęska-Sliwka)

On 21 July 2006 the Police Act was once again amended. According to Article 20 Section (2a) it is now possible to obtain, gather, process and use information (including personal data) while carrying on statutory duties, without the individual's knowledge or consent if he or she is:

- suspected of committing a crime that is prosecuted upon public accusation,
- a minor who committed unlawful acts prosecuted upon public accusation,
- of unidentified personality or tries to disguise his or hers personality,
- fugitive.

However, such data can't be obtained if there is no detection, evidence or identification purpose for an investigation procedure.<sup>60</sup>

Article 20 Section (1) of the Police Act lays down that the police may obtain information, including secret and confidential information, as well as it is entitled to collect, verify and process them, however these activities are subjected to restrictions as set forth by Article 19. According to this provision the police may order an operations audit in the course of its preliminary investigation in order to prevent, detect, identify perpetrators and obtain and secure evidence of intended crimes as set out in Sections (1)-(8). These provisions apply when other measures proved ineffective or there is every likelihood that they will be ineffective or useless. In these cases a district court may order an operations audit under the following conditions:

- at the written request of the Chief Police Commander

- after having received a prior written permit of Attorney General or at the written request of the Voivodeship Police Commander,
- after having received a prior written permit of the appropriate district attorney.

Furthermore Article 20 Section (2) provides that

“for detection and identification purposes, the police may collect, process and utilise information, including personal data, on individuals suspected of indictable offences, juveniles committing acts banned under the law and qualified as indictable offences, as well as unknown persons, persons attempting to conceal their true identity and wanted persons”.

In particular, the police may collect the following information: personal data enlisted in Article 27 Section (1) of the Data Protection Act,<sup>61</sup> on the condition that data in relation to the genetic code concerns exclusively non-coding regions of the DNA.

The Central Forensic Laboratory of the General Headquarters of Police (CFLP)<sup>62</sup> is one of the main providers of forensic services in Poland. The main task of the Laboratory is to provide technical and forensic resources and case-work covering most of forensic specialist areas for police and law enforcement agencies. CFLP is also responsible for the management and maintenance of forensic databases (DNA, Automated Fingerprint Identification System – AFIS) as well as collections of exhibits. The CFLP is operated as a bureau of the Chief Police Headquarters under the supervision of the Ministry of Interior

<sup>60</sup> See A. Gałęska-Śliwka, *Śmierć jako problem medyczno-kryminalistyczny*, Warszawa 2009.

<sup>61</sup> For detailed provision see also Part I. on Classical and population biobanks.

<sup>62</sup> Centralne Laboratorium Kryminalistyczne (CLK) Komendy Głównej Policji (KGP), further information is available at: <http://clk.policja.pl/portals/clk/698/EN.html>

and Administration. The Laboratory's activities are organized in several departments of which the Biology Department is worthwhile to mention in relation to forensic databases.

The DNA Database Unit is operated within the Biology Department of the CFLP. The DNA Database Team performs the collection, analysis and processing of DNA profiles for the police justice system. The team is divided into two groups, one dealing with profiling DNA from evidential material and the other with profiling samples from persons and introducing them in the National Database. Regional forensic laboratories, located nationally and their respective genetic units will deal with the analysis and submission of profiles developed from crime stains to the central database.

#### 4. SAMPLES AND SAMPLE TAKING, CONSENT

Ordinance of 23 February 2005 of the Minister of Justice on the examination and performing other proceedings on persons accused or suspected<sup>63</sup> regulates the procedures of obtaining genetic material for further actions. According to this document, samples from mucus can be obtained when applying special packages branded with individual bar codes. Such actions can be performed only by qualified police officers. However, under special circumstances, it is possible for a

health service or research institute servant to perform such duties.<sup>64</sup>

Filling the information to DNA database is conducted upon a decision made by:

- the authority responsible for preparatory proceedings or court in connection to criminal or juvenile proceedings,
- *ratione loci* competent police authority – in case of unidentifiable individuals, those who are trying to disguise their identity or unidentified corpses.

As it is mentioned above, the police is entitled to conduct operations audit and taking evidence as well as collect, process and store personal data in the course of its preliminary investigation upon the prior permission of the relevant district court. The materials collected in the course of an operations audit shall not be made available to the person subjected to that audit. This provision is not in violation of the rights under Article 321 of the Criminal Proceedings Code which sets out the right of a suspect to access the evidence collected in their case, which also includes materials collected during the surveillance.

According to Article 14 of the Police Act upon fulfilling its statutory duties the police may utilise personal data, including electronic data, that other bodies, services and state institutions have obtained in the course of preliminary investigations and may process the data within the meaning of the Personal Data Act without the knowledge or consent of the individual affected.

<sup>63</sup> Ordinance of 23 February 2005 of the Minister of Justice on the examination and performing other proceedings on accused or suspected (Dz. U. Nr 33, poz. 299) - In original language: Rozporządzenie Ministra Sprawiedliwości w sprawie poddania badaniom lub wykonywania czynności z udziałem oskarżonego oraz osoby podejrzanej.

<sup>64</sup> See E. Gruza, M. Goc, J. Moszczyński: Kryminalistyka – czyli rzecz o metodach śledczych, Warsaw 2008, p. 535.

The administrator of the aforementioned data shall make personal data available pursuant to a request made in the name and after the identification of the police officer requesting it. The request shall be written by the Chief Police Commander, voivodeship police commanders or an authorised police officer.

## 5. PURPOSE AND SCOPE OF COLLECTION

According to the communique of the Ministry of Interior and Administration<sup>65</sup> the National DNA Database contains the following DNA profiles:

*"1. profiles of persons referred to in Articles 74 and 192a of the Code of Criminal Procedure, i.e. defendants, suspects, persons suspected and other persons for whom there were no grounds to remove from the files of the case and destroy the genetic evidence taken from them or recorded earlier,*

*2. profiles of persons whose identity has not been established and of persons who try to conceal their identity,*

*3. profiles of human corpses with identity not established,*

*4. profiles of the traces of unknown crime perpetrators, such as traces found at a crime scene when it is impossible to ascribe them to a particular person."*

The main consequence is that it is possible to:

1. establish connection between traces secured at one location and traces secured at different venues,
2. establish connection between traces secured at crime scene and perpetrator,
3. conduct procedures on unidentified corpse,
4. establish link between DNA profiles established at examination and profiles registered during different procedures.<sup>66</sup>

It also worth mentioning that in 2008 the Polish Police received access to Interpol's DNA database through the International DNA Gateway portal.<sup>67</sup>

## 6. ACCESS TO DATA AND SAMPLES

Considering the detailed regulations in relation to the operation of forensic biobanks in Poland, Article 20 Section (19) of the Police Act also sets forth that the Chief Commander of the Police, following consultations with the Chief Inspector for Data Protection, is responsible for drafting and adopting additional executive legislation concerning the collection, processing, storage and usage of the aforementioned information or data. The Chief Commander of the Police is also obliged to define, by way of a regulation, the manner and procedures for collecting, processing and using information that are collected in the interest of an investigation by the Police pursuant to Section (2)

<sup>65</sup> Polish Police gains access to Interpol's DNA database through the International DNA Gateway portal,

Publication date: 30 July 2008.

[http://www.mswia.gov.pl/portal/en/1/533/Polish\\_Police\\_gains\\_access\\_to\\_Interpols\\_DNA\\_database\\_through\\_the\\_International\\_D.html](http://www.mswia.gov.pl/portal/en/1/533/Polish_Police_gains_access_to_Interpols_DNA_database_through_the_International_D.html)

<sup>66</sup> See M. Goc, J. Moszczyński, op. cit., p. 181.

<sup>67</sup> Polish Police gains access to Interpol's DNA database through the International DNA Gateway portal, Publication date: 30 July 2008.

[http://www.mswia.gov.pl/portal/en/1/533/Polish\\_Police\\_gains\\_access\\_to\\_Interpols\\_DNA\\_database\\_through\\_the\\_International\\_D.html](http://www.mswia.gov.pl/portal/en/1/533/Polish_Police_gains_access_to_Interpols_DNA_database_through_the_International_D.html)

of the same Article, as well as the establishment and management of information databases and to determine a scope of responsibilities of police personnel authorized to use information included in forensic databases, and to prepare documents to be used with data processing with respect to qualified information protection regulations.

## 7. STORAGE

According to Article 20 Section (17) of the Police Act, personal data collected to detect a crime shall be stored for as long as they are needed for the fulfillment of the police's statutory duties. However the Ordinance of 21 February 2005 of the Minister of Justice on Police data processing with respect to investigation or identification purposes<sup>68</sup> states that personal data ought to be removed if:

- an act in connection to which a person was registered had not been committed,
- a person was acquitted by valid court verdict,

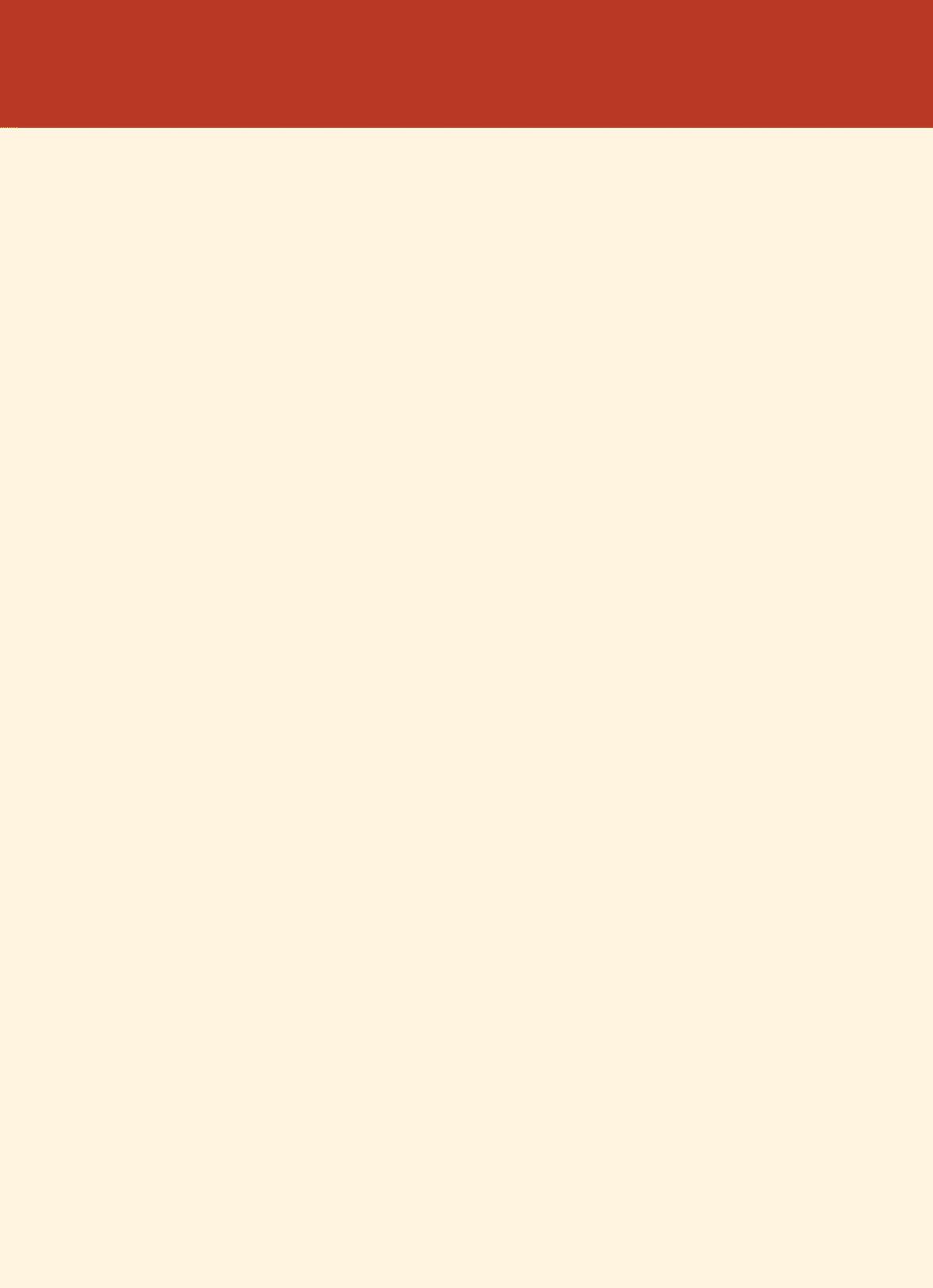
- in case of data verification. Police bodies shall verify the data at least every 10 years from information receipt date and remove obsolete data. Nevertheless Article 20 Section (18) declares that personal data that disclose the race or ethnicity, political views, religious or philosophical attitudes, religion, party or trade union membership, data about health, addictions or sexual relations of persons suspected of a crime prosecuted by a public prosecutor that have not been convicted for those crimes, shall be destroyed promptly after a relevant ruling takes effect. The data shall be destroyed in the presence of a committee and the process shall be evidenced in a report.

DNA data and biological samples are being stored in the Genom database for 20 years, except of individuals suspected, prosecuted or sentenced in connection to crimes laid down in Chapters XVI-XX, XXV and XXXV and Article 94.1 of the Polish Penal Code,<sup>69</sup> as their data and samples are being held for 35 years.<sup>70</sup>

<sup>68</sup> Also Ordinance of 21 February 2005 of the Minister of Justice on data processing with respect to investigation or identification purposes (Dz. U. Nr 34, poz. 313) – In original language: Rozporządzenie Ministra Sprawiedliwości w sprawie przetwarzania przez Policję danych osobowych w celach wykrywczych lub identyfikacyjnych.

<sup>69</sup> XVI Offences against peace, humanity and war crimes, XVII Offences against Republic of Poland, XVIII Offences against defense readiness, XIX Offences against life and health, XX Offences against public safety, XXV Offences against sexual liberty and decency, XXXV Offences against property.

<sup>70</sup> J. Moszczyński, *Badania biologiczne*, ed. E. Gruza, M. Goc, J. Moszczyński, *Kryminalistyka – czyli rzecz o metodach śledczych*, Warszawa 2008, p. 535.





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