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THE LEGAL REGULATION  
OF BIOBANKS

## National Report: Hungary



CENTER FOR ETHICS AND LAW  
IN BIOMEDICINE





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

As partners in the European Union Framework Project entitled “GeneBanC: Genetic bio and dataBanking: Confidentiality and protection of data” we are exploring the legal regulations of data-banks. (<http://www.genebanc.eu/>) The Center for Ethics and Law in Biomedicine established at the Central European University, Budapest (<http://www.ceu.hu/celab>) aimed to investigate the existing regulatory framework of biobanks across the EU and focus on the collection and analysis of legislation and regulation regarding the establishment, management and functioning of classical, population and forensic biobanks across Europe. An important objective was to look at the similarities and differences in such legislation and regulations, in order to formulate recommendations towards a harmonization of European practices and regulations. The European jurisdiction was divided up into two parts between CELAB and the Belgian project partner, the Centre for Biomedical Ethics and Law, K.U.Leuven. CELAB was focusing on the regulatory framework of Cyprus, the Czech Republic, Estonia, Greece, Hungary, Italy, Latvia, Lithuania, Malta, Poland, Romania, the Slovak Republic, and Slovenia. The present booklet is 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 dr. Veronika Karcagi, Ph.D biologist and researcher in human genetics, head of the National Health Institute’s Molecular and Genetic Diagnostics Department for providing us with useful information as to how data acquisition, processing and storage happens in practice. We would also like to express our gratitude to János Woller, Head of Department of Haemogenetics at the Institute for Forensic Sciences for his useful comments on the practical application of the laws in the forensic context.

The present paper summarizes the regulatory framework of biobanks in the Republic of Hungary 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 Hungary being a European Union Member State.

*Budapest, 1 May, 2009*

## I. CLASSICAL AND POPULATION BIOBANKS

### 1. DEFINITION OF BIOBANKS

One specificity of the Hungarian Biobank Act is that it covers exclusively biobanks in the context of genetic research and study. Under the Act *biobank* means a collection of samples containing genetic samples and related genetic and personal identification data for the purposes of a human genetic study or human genetic research. In Article 3 on definitions the law differentiates between *biobanks* and the so called *archived collections* that mean collections containing genetic samples and data stored separately in a biobank in respect of which the original purpose of the sampling has already been fulfilled.

In order to present the wider landscape of Hungarian legislation we have however understood biobanks differently: as a collection of human biological material stored jointly with related information data, and addressed the regulatory framework accordingly.

### 2. RELEVANT LAWS

#### 2.1. The Biobank Act of 2008

Since 2002 there have been many attempts to make a law on the protection of genetic data and on the regulation of biobanks in Hungary. The debates on the ethical and legal issues of human genetic data have started already in the circles of the Health Science Council. Several experts on genetics, molecular biology and social sciences called the attention on the special challenges of genetics. Thematic issues were published in two major science and social science journals: in 1999 in *Világosság*<sup>1</sup> and in 2002 in *Magyar Tudomány*<sup>2</sup>. The draft of the legal concept was ready for the public consultation already in 2003. However, the Ministry was instabile during the entire period between 2002-2008. While wrestling with the health care reform none of the Ministers survived more than one year in office.

<sup>1</sup> The title of the Special issue was “*Bioethics and Human Rights*”, authors included Vilmos Csányi, Noëlle Lenoir, Henk ten Have, Judit Sándor, Pál Venetiáner. First time the text of the Universal Declaration on Human Genome and Human Rights were published in Hungary together with the Articles on human genetics and human rights. *Világosság*, 1999/2 Vol.XL. February

<sup>2</sup> Special issue of *Magyar Tudomány* on the Human Genome Project was edited by Pál Venetiáner. Authors were: György Kosztolányi, László Patthy, Eörs Szathmáry, István Raskó, Péter Arányi, György Kampis, Judit Sándor and Pál Venetiáner *Magyar Tudomány*, 2002/5. Vol. XLVII.

The result of this legislative process is the Parliamentary Act XXI of 2008 on the protection of human genetic data and the regulation of human genetic studies, research and biobanks (hereinafter referred to as “Biobank Act”).<sup>3</sup> The Biobank Act entered into force on 1 July, 2008. One may state that it has become shorter and simpler than in the original policy paper in a desperate effort to avoid sensitive issues. Thus, the law addresses the use of genetic information only in the very narrow biomedical sector: in the fields of genetic testing, screening, and research. The law restricts the use of genetic data only in this biomedical context so even in the lack of regulation of the broader use of genetic data based on the Act genetic data processed for diagnostic or research purposes cannot be disseminated for the purposes of insurance.

In Article 1 of the Biobank Act the purpose of the law is stated as “to lay down rules on human genetic tests and screening (studies) and human genetic research, the conditions and purposes of the treatment of genetic data and rules on biobanks.” The Act applies to genetic sampling for human genetic study and human genetic research performed under the Act on the territory of the Republic of Hungary, the processing of genetic data irrespective of the place of sampling, and to genetic testing and screening and human genetic research and to biobanks.

According to Article 30 collections of cells, tissue samples or other human biological materials established for genetic research or genetic diagnostics

prior to the entry into force of the Act, excluding tissue banks for transplantation purposes and gamete banks for gamete donation and deposit, shall comply with the rules on biobanks of the Act by 1 October 2009.

Genetic samples and data anonymised in accordance with the requirements of the Biobank Act even before its entry into force may be treated in line with the Act for human genetic research and study.

The entry into force of the Biobank Act is certainly not the last step in the Hungarian regulation of biobanks. Article 31 of the Act delegates legislation to the Minister of Health, who is empowered to lay down in Ministerial Decrees *a)* detailed rules of genetic tests and screenings, *b)* minimum conditions of the operation of laboratories engaged in genetic tests and screenings, *c)* accreditation and quality control requirements against laboratories engaged in genetic testing and screening, *d)* detailed rules of the storage, treatment, processing of genetic samples and genetic data and the encoding of genetic data, *e)* professional minimum conditions of the operation of the biobank and the aspects of authorisation, and *f)* formal requirements of the declaration of consent.

## 2.2. Other pieces of relevant laws

The enumeration of domestic legal instruments other than the Biobank Act will follow the hierarchy of laws in the Hungarian legal system. Accordingly the list of Acts will be followed by the decrees of the respective ministries.

<sup>3</sup> In original language 2008. évi XXI. törvény a humán genetikai adatok védelméről, a humán genetikai vizsgálatok és kutatások, valamint a biobankok működésének szabályairól, available at <http://www.complex.hu/kzldat/t0800021.htm/t0800021.htm>

The various norms that are on the same level of the hierarchy will be discussed by starting from the more specific targeted legislation and move towards the general laws.

There are two Acts applicable to biobanks: Act XLVII of 1997 on the Processing and Protection of Health Care Data and Associated Personal Data<sup>4</sup> (hereinafter referred to as “Health Care Data Act”) being more specific and Act LXIII of 1992 on the Protection of Personal Data and Public Access to Data of Public Interest<sup>5</sup> (hereinafter referred to as “Data Protection Act”). As background legislation, the Act CLIV of 1997 on Health Care<sup>6</sup> (hereinafter referred to as “Health Care Act”) and the Act IV of 1959 on the Civil Code of

the Republic of Hungary<sup>7</sup> (hereinafter referred to as “Civil Code”) may also provide guidance.<sup>8</sup>

In reverse chronological order the following decrees are biobank-related: Ministerial Decree 3/2005. (II. 10.) of the Ministry of Health on Standards of Quality and Safety for the Collection, Testing, Processing, Storage and Distribution of Human Blood and Blood Components, and Certain Technical Requirements,<sup>9</sup> Ministerial Decree 76/2004 (VIII. 19.) of the Ministry of Health, Welfare and Family on the Detailed Rules of the Determination, Collection and Processing of the Scope of Certain Specialized (Health, Professional) Data Incapable of Identification,<sup>10</sup> Ministerial Decree 23/2002 (V.

<sup>4</sup> In original language: 1997. évi XLVII. törvény az egészségügyi és a hozzájuk kapcsolódó személyes adatok kezeléséről és védelméről, available at [http://net.jogtar.hu/jr/gen/hjegy\\_doc.cgi?docid=99700047.TV&jab=1](http://net.jogtar.hu/jr/gen/hjegy_doc.cgi?docid=99700047.TV&jab=1), adopted on 5 June, 1997, entering into force on 1 January, 1998.

<sup>5</sup> In original language: 1992. évi LXIII. törvény a személyes adatok védelméről és a közérdekű adatok nyilvánosságáról, available at [http://net.jogtar.hu/jr/gen/hjegy\\_doc.cgi?docid=99200063.TV&jab=1](http://net.jogtar.hu/jr/gen/hjegy_doc.cgi?docid=99200063.TV&jab=1), adopted on 17 November, 1992, entering into force on 1 May, 1993. The amendment to the Data Protection Act in 2003, which entered into force on 1 January 2004, follows both the conceptual and institutional system described in the Directive 95/46/EC. Hungary is also a party to the data protection convention of the Council of Europe (ETS 108).

<sup>6</sup> In original language: 1997. évi CLIV. törvény az egészségügyről, available at [http://www.complex.hu/kzldat/t9700154.htm/t9700154\\_0.htm](http://www.complex.hu/kzldat/t9700154.htm/t9700154_0.htm), adopted on 15 December, 1997, entering into force on 1 July, 1998. (with the exception of certain provisions indicated in Article 245)

<sup>7</sup> In original language: 1959. évi IV. törvény a Polgári Törvénykönyvről, available at [http://net.jogtar.hu/jr/gen/hjegy\\_doc.cgi?docid=95900004.TV](http://net.jogtar.hu/jr/gen/hjegy_doc.cgi?docid=95900004.TV), adopted on 11 August, 1959, entering into force on 1 May, 1960 through the force of a special Decree. A comprehensive text including modifications of the Civil Code has been adopted through Act IV of 1977 on 25 October, 1977, and it entered into force on 1 March, 1978. The above link refers to the comprehensive and latest text of the Civil Code.

<sup>8</sup> The new draft of the Civil Code does not foresee any substantial changes from the point of view of the topic. See [http://www.irm.hu/download/ptk\\_szemelyek.pdf/ptk\\_szemelyek.pdf](http://www.irm.hu/download/ptk_szemelyek.pdf/ptk_szemelyek.pdf)

<sup>9</sup> In original language: 3/2005. (II. 10.) EüM rendelet az emberi vér és vérkomponensek gyűjtésére, vizsgálatára, feldolgozására, tárolására és elosztására vonatkozó minőségi és biztonsági előírásokról, valamint ezek egyes technikai követelményeiről, available at <http://net.jogtar.hu/jr/gen/getdoc.cgi?docid=A0500003.EUM>, adopted on 10 February, 2005, entering into force on 13 February, 2005.

<sup>10</sup> In original language: 76/2004. (VIII. 19.) ESzCsM rendelet az egyes személyazonosításra alkalmatlan ágazati (egészségügyi, szakmai) adatok körének meghatározására, gyűjtésére, feldolgozására vonatkozó részletes szabályokról, available at [http://net.jogtar.hu/jr/gen/hjegy\\_doc.cgi?docid=A0400076.ESC](http://net.jogtar.hu/jr/gen/hjegy_doc.cgi?docid=A0400076.ESC), adopted on 19 August, 2004, entering into force on 1 September, 2004.

9.) of the Ministry of Health on the Medical Research Conducted on Humans,<sup>11</sup> and Ministerial Decree 62/1997 (XII. 21.) of the Ministry of Welfare on the Processing of Health and Related Personal Data.<sup>12</sup>

### 3. ESTABLISHMENT AND MANAGEMENT OF BIOBANKS

According to Article 22 Section (1) of the Biobank Act a biobank may be established and maintained by a health service provider authorised to conduct genetic studies and certain medical researches by the health service authority.

A research plan may be authorised only in the event that the institution engaged in human genetic research has a biobank or avails of conditions related to the establishment and maintenance of a biobank under the Act and other relevant pieces of legislation. The operation of a health service provider engaged in human genetic research may be authorised under the same conditions.

### 4. PECUNIARY ASPECTS

The collection and storage of data in research biobanks are free. Cord blood banks prove to be an exception from this general rule. Donors are not remunerated, neither do they receive any other benefits.

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

According to Article 6 of the Biobank Act prior to sampling the person concerned has to be informed, as a part of the genetic counselling, of the purpose of the sampling, advantages and risks of participating or not participating in the study, possible consequences to the person concerned and their close relatives of any outcome, methods of the storage of the genetic sample and data, possible identification of genetic samples and data stored in different formats.

When the genetic sample is used for research, the person concerned shall be informed about the provisions of Article 159 Section (3) of the Health Care Act before signing the declaration of consent, on methods of the storage of the genetic sample and data, possible identification methods of genetic samples and data stored in different formats, and the inclusion into an archived collection of the genetic sample in the absence of another declaration by the person concerned, and the possible forwarding of stored genetic samples.

The person concerned shall be entitled to know the result of the human genetic study in a consultation that is specifically tailored to his or her needs. During the consultation the person

<sup>11</sup> In original language: 23/2002. (V. 9.) EüM rendelet az emberen végzett orvostudományi kutatásokról, available at [http://net.jogtar.hu/jr/gen/hjegy\\_doc.cgi?docid=A0200023.EUM&jab=1](http://net.jogtar.hu/jr/gen/hjegy_doc.cgi?docid=A0200023.EUM&jab=1), adopted on 9 May, 2002, entering into force on 24 May, 2002.

<sup>12</sup> In original language: 62/1997. (XII. 21.) NM rendelet az egészségügyi és a hozzájuk kapcsolódó személyes adatok kezelésének egyes kérdéseiről, available at [http://net.jogtar.hu/jr/gen/hjegy\\_doc.cgi?docid=99700062.NM](http://net.jogtar.hu/jr/gen/hjegy_doc.cgi?docid=99700062.NM), adopted on 21 December, 1997, entering into force on 1 January, 1998.



concerned shall be assisted in the long-term processing of the possible consequences of the result and the choice of optimum treatment opportunities.

The “right not to know” is respected by the law by saying that the person concerned may withdraw from knowing their genetic data by a declaration. The declaration is subject to withdrawal any time without restriction. The person concerned shall be informed about this right, too.

According to Article 8 Section (1) before a genetic sampling, it is necessary to obtain the written consent of the person entitled to disposal based on detailed information, irrespective of the purpose of the treatment of the genetic data.

The Hungarian Biobank Act is built on the respect to self-determination of the individual concerned. Articles 8-11 deal with this right in details. In order to be valid the consent to sampling has to include several elements:

- a) the statement of consent by the person concerned to the following:
  - aa) taking genetic sample from him or her,
  - ab) storing the genetic sample and the derived genetic data in a biobank and to forward it to another biobank,
  - ac) storing the genetic sample and the derived genetic data in an archived collection;
  - b) declaration of the person concerned to the effect that they give their consent to
    - ba) the use for the primary purpose of sampling,
    - bb) the use for any purpose under the Biobank Act apart from the provisions of point ba) and

bc) the use for research of the genetic sample and data only;

- c) the declaration of the person concerned according to which he or she gives their consent to the storage of the genetic sample and data together with personal identification data, or the storage of the same in an encoded or, in the case under subpoint bc) of point b), in a pseudonym or anonymised format;
- d) the declaration of the person concerned of having received and understood the information on the purpose of the sampling, advantages and risks of participating or not participating in the study, possible consequences to the person concerned and their close relatives of any outcome, methods of the storage of the genetic sample and data, possible identification of genetic samples and data stored in different formats, furthermore the information under Article 159 Section (3) of the Health Care Act, and finally information about the details as to who has access to his or her genetic data.

During the storage of the encoded genetic sample or data, the person concerned may be identified only for the interest of the person concerned or his or her close relative according to Article 8 Section (4) of the Biobank Act.

In the absence of a declaration when the person concerned does not expressly refuse it, the genetic samples and data may be placed in an archived collection in anonymised format.

With Article 9 in line genetic sampling from a deceased person, the study of a genetic sample stored together with personal identification data or a sample which has been encoded,

their use for human genetic research or the use of derived genetic data is possible only when the deceased person did not make a declaration objecting to it in their lifetime.

In case of verbal consent the declaration shall be documented in writing with the signature of the two witnesses proving the occurrence of the oral declaration. An oral declaration made with the medical practitioner, signed by two witnesses or a declaration at his or her disposal otherwise shall be recorded in writing in the health documentation by the medical practitioner or shall be attached to the latter.

According to Article 10 Section (1) the person concerned may withdraw his or her consent to the treatment of their genetic data being stored together with his or her personal identification data, code or pseudonym at any time. For a declaration of withdrawal, the person concerned may request that the genetic sample and all the derived genetic data be destroyed.

According to Article 10 Section (2), the genetic sample and data shall be destroyed immediately but within 8 days at the latest for sample and data used for human genetic research purposes only, and following the 30<sup>th</sup> day after the submission of the request for samples and data stored for genetic research, within 45 days following the request. Following the receipt of the request, genetic samples and data may be treated in the interest of a close relative only.

According to Article 7 when necessary for the prevention of an illness of a close relative, the knowledge of the nature of their illness, their therapy or the assessment of the risk of illnesses for their descendants, the genetic data

may be communicated to a close relative as well. For this purpose, the medical practitioner shall call the attention of the close relative known by them to the necessity of knowing genetic data in the framework of a genetic counselling or shall initiate the involvement of the direct relative into the genetic counselling with the person concerned.

Samples can be taken from persons under 14 years, i.e. persons without legal competency, or from persons between 14 and 18 years of age who under the Hungarian system are persons with limited legal competency. Similarly samples can also be taken from mentally challenged persons. In all these cases the guardian, in case of children typically the parent gives consent. According to Article 8 Section (2) persons with limited competency may consent with the prior agreement of the legal representative, or with the additional approval of the consent of the person with limited competency. Genetic samples must not be taken until the approval. In case of persons without a legal competency only the legal representative may consent, but only by taking Article 13 Sections (3) and (4) laying down the exceptional rules when persons without legal competency may be subjected to human genetic research. As to the withdrawal of the consent, the same procedure applies according to Article 8 Section (8). A declaration objecting to the genetic sampling after death can be made by persons of limited legal capacity even without the legal representative's consent or approval according to Article 9 Section (4).

Background pieces of legislation applicable to persons without and with

limited legal competency are the following: according to Article 11 of the Civil Code, everybody whose competency is not limited or disqualified by the law is legally competent. Whosoever is competent is entitled to conclude contracts and make other legal statements. According to Article 12 of the Civil Code persons who have not yet reached the age of eighteen years shall be deemed minors, unless they are married. Article 12/A states that a minor shall be of partial capacity if he or she has reached the age of fourteen years and is not incompetent. Unless otherwise provided by law – and as to informed consent there is no such law – the legal statement of a minor with partial capacity shall not be deemed valid without the subsequent approval or consent of that person’s legal representative. If and when minors of partial capacity become competent, they shall be entitled to make their own decisions concerning the validity of their pending legal statements. According to Article 12/B minors under the age of fourteen years are legally incompetent. According to Article 12/C legal statements made by incompetent minors shall be null and void; their legal representatives shall proceed on their behalf.

According to Article 16 Section (2) of the Health Care Act if a patient has no, or limited disposing capacity, the following persons, in the following order are entitled to exercise the right of consent: the patient’s legal representative, in the absence thereof the following people sharing household with the patient: the patient’s spouse or common-law spouse, in the absence thereof, the patient’s child, in the absence thereof, the patient’s parent, in the absence thereof, the patient’s

sibling, in the absence thereof, the patient’s grandparent, in the absence thereof, the patient’s grandchild. If there is nobody sharing household from the above mentioned enumeration of persons, than the same relatives in the same order not sharing household may consent, i.e. the patient’s child, parent, sibling, grandparent, or grandchild.

As to persons whose competency is limited or precluded by order of guardianship there are special rules. Article 14 Section (5) of the Civil Code covers those persons whose loss of discretionary ability is only partial: these persons under guardianship are themselves able to make legal statements in all matters where the court did not limit their competency in its ruling restricting legal competency. Article 14 Section (6) lays down the subject matters where the legal competency of persons placed under guardianship may be completely restricted by court order, and the enumeration includes the exercise of rights in connection with health care. According to Article 14/B Civil Code by general principle or in respect of the matters specified in the court ruling the legal statement of a person with partial capacity is not be deemed valid without the subsequent approval or consent of that person’s legal representative. Any disagreement between the conservator and the person in his custody is to be resolved by the guardian. If and when persons of partial competency become competent, they are entitled to make their own decisions concerning the validity of their pending legal statements. Article 15 Civil Code is applicable to legally incompetent persons, i.e. those persons of legal age whom the court has

placed in a guardianship precluding legal competency.

As Article 15/A Civil Code lays down legal statements made by incompetent persons shall be null and void; their guardian shall proceed on their behalf. Prior to making a decision the guardian shall hear the views and requests of the person in his custody, if that person is of sound mind, and shall abide by such requests if possible.

## 6. ACCESS TO DATA AND SAMPLES AND ANONYMITY

One of the specificity of the Biobank Act is that it regulates three different levels of coding and anonymity, in Article 3 points d), e) and f)

- *the encoded genetic sample or data* meaning genetic sample or data regarding which all the personal identification data relating to the person giving the sample are replaced by a code;

- *pseudonym genetic sample or data* meaning encoded genetic sample or data regarding which the code replacing the personal identification data was provided to the person concerned;

- *anonymised genetic sample or data* meaning genetic sample or data regarding which all the personal identification data relating to the person giving the sample was made incapable of identifying the person.

Biobank may provide another biobank or an entity with a proper research authorisation for the purposes of the Act with genetic samples or data apart from the field of activities of the institution establishing the biobank only. The health authority shall keep a register, separate from that of health service providers, on biobanks and institutions storing genetic samples

and data under a valid research authorisation which shall be publicly accessible. Data necessary for keeping the register shall be provided by authorities and persons authorising the operation and the research plan immediately following the issue of the authorisation. The register may not contain genetic data.

Rules on biobanks shall be applied by every collection of cells, tissue samples or other human biological materials established for the purposes of research and treatment.

The authorisation of the health authority shall be required for transformation into a biobank and for the establishment of a biobank.

Chapter VI covers the data and sample transfer abroad within and beyond the territory of the European Union. Under Article 29 human genetic research, data transmission to EEA States shall be considered to be data transmission within the territory of the Republic of Hungary.

For the purposes of human genetic research, only anonymised, encoded or pseudonym genetic samples or data may be transmitted to third countries and only when the law of the given country provides for data protection corresponding to that under the Biobank and the Data Protection Acts. During the transmission into third countries of encoded genetic samples and data, the code key necessary for personal identification may not be transmitted.

For the purposes of human genetic study, only encoded genetic samples may be transmitted to third countries. Genetic sample or data may enter the territory of Hungary only from a third country where requirements are laid

down in the Hungarian law are ensured. Proof necessary for the checking of this shall be obtained by the health authority.

Other relevant provisions can be found in the Hungarian data protection legislation, which is a complex body of law comprising of several acts, the Data Protection Act being the most important general law, and the Health Care Data Act being the primary specific, sectorial piece of legislation.

Under the Data Protection Act personal data is defined as any piece of data related only to an (identified or identifiable) natural person, i.e. data related to legal bodies are not covered. According to Article 2 of the Data Protection Act personal data are data which can be associated with a person, and the conclusion, which can be drawn from the data, relating to the person concerned. Personal data keep their above defined quality in the course of data handling until their connection with the person concerned can be restored. Special data are personal data relating to racial origin, national, nationality and ethnic status, political opinion or party affiliation, religious or other conviction, health condition, abnormal addiction, sexual life and criminal record. Hungarian law recognises the right to the protection of personal data as a core constitutional right, also called the right of informational self-determination. The affected person always has the right to decide about the handling of his or her personal data: he or she may amend or revoke his or her consent for data handling at any time, without justification. When consent is revoked, personal data already recorded must be deleted.

Chapter II of the Health Care Data Act provides a list of objectives for data management, including data processing for scientific research purposes. According to Article 21 the director of the institution or the data manager may authorize for research purposes access to stored data, however in scientific publications health and personal data may not be indicated in a way capable of identifying persons. Copies cannot be made of the stored data if personal data are also visible. A register is to be maintained listing the persons who accessed the stored data, their objectives, the time and date of access. This register is to be maintained for a minimum of 10 years. In case the director of the institution or the data manager denies access to data, he or she has to justify such a decision in a written way. The person requesting data may turn to the court against a negative decision.

Health service providers processing data create unique data processing systems. Rules on these systems are to be laid down in a so-called Data Protection Protocol compiled by the health service provider. According to Article 3 Section (1) of the Ministerial Decree 62/1997 (XII. 21.) of the Ministry of Welfare on the Processing of Health and Related Personal Data special attention is to be made as to the rules on access for the protection of health data; the rules necessary for the protection of integrity of health data; and the rules on ensuring access to health data and data supply as regulated by the Act XLVII of 1997 on the Processing and Protection of Health Information and Related Data.

The necessary content elements of the Data Protection Protocol are the following according to Article 3 Section

(2) of the Ministerial Decree 62/1997. (XII. 21.) of the Ministry of Welfare on the Processing of Health and Related Personal Data:

- a) general security rules of the data processing system,
- b) detailed regulation of the data processing system and its operation, such as
  - ba) the rights and obligations of the person responsible for data protection,
  - bb) the protection of the data processing system's environment,
  - bc) measures planned for the prevention of the data being damaged or lost, steps to be taken for the mitigation of consequences,
  - bd) measures planned in case the data processing system is being damaged,
  - be) rules for the protection of data against appropriation,
  - ca) identification of the data processor, access to and exit from the data processing system,
  - cb) identification of groups of data on the basis of data processors,
  - cc) registration of the entitlement of data processors,
  - d) controllability of health-related documents in the given data processing system
    - da) regulation of the data processing system's administration,
    - db) identification of the origin of data,
    - dc) measuring the correctness, genuineness of data,
    - dd) the regulation of data traffic from and to the data processing system,
  - e) technological, operational reliability of the data processing system,
  - f) technological regulation of the sustainability of the data processing system,
    - fa) regulation of the data processing system's maintenance,
    - fb) the regulation of provisions applicable to the documentation of the data processing system,
    - fc) rules on the modification of the data processing system, interim provisions for the period of technical modification and development,
    - g) rules on data processors:
      - ga) the regulation of data protection issues concerning the labor law relations of data processors,
      - gb) the separation of tasks concerning data processing and maintaining or developing the data processing system,
      - gc) the regulation of the data protection training,
      - gd) the regulation of data protection reporting obligations,
    - h) the rules on health documentation, and on the storage, destruction and archiving of the final medical report.

According to Article 2 Section (3) the Data Protection Protocol shall be reviewed if necessary, but in every three years at the minimum.

Article 2 of Ministerial Decree 76/2004 (VIII. 19.) provides that health related data may be used in a form incapable of identification of persons for the following purposes: the fulfillment of international obligation of data providing, decision on health policy, the planning and organization of health services, the monitoring of public health data indicators, and the controlling of the realization of quality and

<sup>13</sup> These objectives are listed in Article 20 Section (4) of the Act XLVII of 1997.

security requirements.<sup>13</sup> The Decree also determines which health care providers have to provide data, the addressee of the information, at what frequency, under what deadlines data are to be submitted, and the registration numbers are also determined.

## 7. STORAGE

The fifth part of the Biobank Act provides for rules on the operation of biobanks. By legislating on the operational rules of biobanks, the conditions of the operation of collections containing human biological material samples will be established. Accordingly, the genetic samples, and data shall be stored only in biobanks, and, as a general rule, in a format determined by the declaration of consent of the person concerned. There is a safeguard provision laying down the conditions of the storage of the genetic sample or data in a way that allows personal identification and prohibits a register containing such data together with personal identification data. It is stated that a biobank may be established and maintained by a health service provider authorised to conduct genetic studies and certain medical researches or other institutions entitled to conduct human genetic research only. The Biobank Act provides for the tasks of the responsible person being employed in the biobank, the keeping of data stored in the biobank and the forwarding of data as well as the register of biobanks.

According to Article 24 during the storage of the genetic sample or data, the protection of the genetic sample or data shall be ensured against destruction, termination, change, injury, publication or access by unauthorised persons.

Unless provided otherwise by this Act, genetic samples and data shall be stored in an encoded format. Encoded genetic samples, data and code keys shall be stored separately, both physically and electronically. Access to the code key shall be authorised to a person being responsible under Article 23 within the framework of the Biobank Act. During the separate storage of the code key, it shall be ensured that no other person may access it apart from the person entitled thereto. The code of the pseudonym sample or data shall be put at the exclusive disposal of the person providing the sample.

According to Article 24 Section (1) genetic sample or data may be stored together with personal identification data only subject to the consent of the person concerned. Section (2) provides that a register containing genetic samples and data stored together with personal identification data or encoded genetic samples and data may not be linked to a register containing personal identification data.

According to Article 25 Section (1) within the biobank, the person responsible for the protection of genetic samples and genetic data, the registering of genetic samples and data and the keeping of the register shall be the head of the institution maintaining the biobank and the person designated by the latter for the supervision of the operation of the biobank.

According to Article 26 Section (1) every genetic sample and data stored in the biobank and all related procedures and activities and the forwarding of the genetic sample and data shall be registered for at least 30 years following the recording of the data, except when the person concerned withdraws

their consent to the treatment of genetic data. In such a case, every register relating to genetic data shall be destroyed following the information of the person concerned. Following the mandatory registration period, the data can be handled according to the Health Care Data Act. The register may be an electronic one.

The register shall contain the types, quantities, origins and destination of collected, studied, stored, processed and distributed or otherwise used genetic samples and the genetic data derived from these. The biobank may forward non-anonymised genetic data only within the framework of the declaration under Article 8 Section (1) of the person concerned. The forwarding of data exceeding the framework of the declaration of consent under Article 8 Section (1) shall necessitate repeated consent from the person concerned.

## 8. SUPERVISION, COMPENSATION, PENALTIES

As already noted, according to Article 22 Section (1) of the Biobank Act a biobank may be established and maintained by a health service provider authorised to conduct genetic studies and certain medical researches by the health service authority.

According to Article 25 Within the biobank, the person responsible for the protection of genetic samples and genetic data, the registering of genetic samples and data and the keeping of the register shall be the head of the institution maintaining the biobank and the person designated by the latter for the supervision of the operation of the biobank (hereinafter referred to as person responsible).

The detailed rules on accreditation and quality control requirements against laboratories engaged in genetic testing and screening, and the aspects of authorisation will among others be regulated by Ministerial Decrees.

## 9. PUBLIC DEBATE

Hungary does not have an institutionalized deliberative mechanism to involve the broader segments of society into a potentially lengthy discussion of issues related to new technologies. As a consequence, ethical and social implications of biotechnological advances are discussed only in narrow professional circles. Although the adoption of the Act took more than five years, the time did not enrich the preliminary draft with more thoughts, the text did not become more detailed, instead problematic issues were simply cut out from the text. As a result instead of making a comprehensive law on the use and processing of human genetic data in various fields, the law adopted by the Parliament exclusively focused on the diagnostic and therapeutic use and the biomedical research.

Despite the intended laconic law the mere word “genetics” was a calling for a vehement debate by various political actors. Fears of genetic discrimination, exploitation or trafficking data to foreign countries were the major concerns in the political debate. Maybe it is not an exaggeration to say that this law served as a learning exercise for the wider public on contemporary ethical issues in genetics.

Even earlier in the course of the legislative debate lawyers, data protection activists were mobilized and advocated



for newer and newer guarantees for the protection of genetic data. Since the original concept was proposed in 2003, several biobanks have started to operate and the scientists started to worry about the legal vacuum. Biobanks were established in an *ad hoc* fashion mainly attached to teaching hospitals or departments at the university systematically collecting disease specific biological samples. As a result of this new phenomenon the scope of the law was slightly shifted from the issues of genetic research toward biobanks. At the end the law developed a restricted notion of biobanks; only those that process genetic data. The issues of data protection were so dominant in the debate that some other, broader human rights aspects were entirely left out from the final version of the law.

By focusing on the data protection and creating a stronger protection for the genetic data some other elements of the ethical-legal framework were sacrificed, such as the prohibition of discrimination based on genetic characteristics was referred to general laws and relatively little public consultations were conducted on biobanks in Hungary. Data protection rules, including the protection of the health care data are fragmented and dispersed in

various norms. Several Bills have failed during the legislative process since 2003, before the current version on the protection of personal genetic data, genetic diagnoses, and genetic research was finally adopted. György Kosztolányi and Judit Sándor, together with the members of the Health Science Council<sup>14</sup> have published a *Preliminary Expert Concept* in relation to the Parliamentary Bill on the Protection of Personal Genetic Data, Genetic Research, Tests, and Biobanks.<sup>15</sup> Another paper of the Medical Research Council, the Position Paper of the Scientific Health Council on the Medical, Ethical and Legal Background of Stem Cells Gained from Cord Blood may also give some guidance.<sup>16</sup>

At the beginning of the legislative process in 2003, the Minister for Health launched an invitation for public consultation and published the proposal on its website. The consultation was based on of the Oviedo Convention.<sup>17</sup> It should be noted that it was the first public consultation in the field of biotechnology and law. Since then several open hearing days were organized in the Parliament around burning social issues, such as the health insurance reform for instance.

Furthermore, a Hungarian medical periodical, *Lege Artis Medicinæ* also

<sup>14</sup> In Hungarian: Egészségügyi Tudományos Tanács, see <http://www.ett.hu/>.

<sup>15</sup> In original language: “Előzetes szakmai koncepció a személyes genetikai adatok védelméről, a genetikai kutatásokról, teszt- és szűrővizsgálatokról, valamint a biobankokról szóló törvényjavaslatához,” available at [www.ett.hu/lapok/tajkoztato/humgen.pdf](http://www.ett.hu/lapok/tajkoztato/humgen.pdf).

<sup>16</sup> In original language: “Az ETT állásfoglalása a köldökzsinórvérből nyert őssejtek felhasználásának orvosszakmai, etikai és jogi hátteréről,” available at <http://www.ett.hu/lapok/allasfoglalas/ossejt.pdf>.

<sup>17</sup> As Article 28 of the Convention states: “Parties to this Convention shall see to it that the fundamental questions raised by the developments of biology and medicine are the subject of appropriate public discussion in the light, in particular, of relevant medical, social, economic, ethical and legal implications, and that their possible application is made the subject of appropriate consultation.”

published the first draft and called experts for consultation. The proposal was made with an open call on the website of the Ministry. Some civil organizations, civil liberty organizations (such as the Hungarian Civil Liberties Union) participated in the debate that resulted in the amended version of the first draft.

In addition to the above mentioned actors, the Parliamentary Commissioner on Data Protection, the Health Science Council several academics, experts, medical and other professional organizations participated in the debate and submitted written opinions with proposed amendments.

Uncertainties about the various kinds of biobanks, and the fear of opening a debate on pre-implantation genetic testing, postponed the approval of the

Bill several times. Some opponents were against this law because they saw it as a sign of genetic exceptionalism while the Ministry for Justice raised repeatedly concerns for even a stronger protection of genetic data. In December 2006 an expert meeting was held at the Ministry for Health as a result of which the Bill was again modified and discussed within the Ministries and the debate was reopened again in 2007. The Parliament started the discussion of the Bill in March 2008.

After many years of debate a very short and simplified version of the original concept was adopted in April, 2008, the Biobank Act. This law engages with the strong protection of genetic data and as such follows the tradition of the data protection norms in Hungary.

## II. FORENSIC BIOBANKS

### 1. RELEVANT LAWS

Act LXXXV of 1999 on the Criminal Records and Certificates on Criminal Record is the primary Hungarian law regulating specifically forensic biobanks (hereinafter referred to as “Criminal Records Act”).<sup>18</sup> Lower pieces of legislation are Decree 8/2000. (II. 16.) of the Ministry of Interior, the Ministry of Justice, and the Ministry of Finance on the Rules of Fingerprints, Palm Prints, Taking Photographs, and DNA Samples<sup>19</sup> and Decree 7/2000. (II. 16.) of the Ministry of Interior and the Ministry of Justice on the Authority Handling Criminal Records, and on the Rules of Disclosure and Supplying of Data.<sup>20</sup>

It shall be noted that the Hungarian legislation does not talk about bio-

banks in the forensic context. The word biobank is exclusively used in the biomedical sector, and has first been introduced by the legislative power through Act XXI of 2008 on the protection of human genetic data and the regulation of human genetic studies, research and biobanks. The repository of samples and information kept by the Institute for Forensic Sciences is officially called DNA database. This is the databank that we refer to as forensic biobank for the purposes of the present summary.

### 2. MANAGEMENT AND SUPERVISION

Act LXIII of 1992 on the Protection of Personal Data and Public Access to Data of Public Interest serves as the

<sup>18</sup> In original language: 1999. évi LXXXV. törvény a büntügyi nyilvántartásról és a hatósági erkölcsi bizonyítványról, available at [http://net.jogtar.hu/jr/gen/hjegy\\_doc.cgi?docid=99900085.TV&jab=1](http://net.jogtar.hu/jr/gen/hjegy_doc.cgi?docid=99900085.TV&jab=1), adopted on 15 November, 1999, entering into force on 1 May, 2000.

<sup>19</sup> In original language: 8/2000. (II. 16.) BM—IM—PM együttes rendelet az ujj- és tenyérnyomatvételezés, a fényképezés, valamint a DNS-mintavétel szabályairól, available at [http://net.jogtar.hu/jr/gen/hjegy\\_doc.cgi?docid=A0000008.BM&jab=1](http://net.jogtar.hu/jr/gen/hjegy_doc.cgi?docid=A0000008.BM&jab=1), adopted on 16 February, 2000, entering into force on 1 March, 2000.

<sup>20</sup> In original language: 7/2000. (II. 16.) BM—IM együttes rendelet a büntügyi nyilvántartást kezelő szervről, az adatközlés és az adatszolgáltatás rendjéről, available at [http://net.jogtar.hu/jr/gen/hjegy\\_doc.cgi?docid=A0000007.BM&jab=1](http://net.jogtar.hu/jr/gen/hjegy_doc.cgi?docid=A0000007.BM&jab=1), adopted on 16 February, 2000, entering into force on 1 March, 2000.

primary background legislation.<sup>21</sup>

The main forensic biobank is managed by the Hungarian police, and is supervised by the Ministry of Justice and Law Enforcement.

### 3. SAMPLES AND SAMPLE TAKING, CONSENT

Samples collected, stored and processed are DNA, saliva and hair. According to Article 43 of the Criminal Records Act the investigation authorities take measures concerning the sampling of oral mucous membrane or hair in case of the commencement of a criminal proceeding due to a well-founded suspicion of a crime. Sampling is to be done by securing the physical integrity of the suspect.<sup>22</sup>

Persons against whom criminal proceedings have been initiated on the grounds of a well-founded suspicion have to subject themselves to the sampling procedure, and forebear the taking of the DNA sample. Should they fail to comply with this obligation, physical coercion may be used. In neither of the cases does sample taking amount to a violation of physical integrity.<sup>23</sup> As the above show, consent is not a necessary requirement for sample taking, however the suspect has to be informed about the fact that the sample is taken for the sake of DNA testing.<sup>24</sup>

### 4. PURPOSE AND SCOPE OF COLLECTION

Samples are taken from certain suspects, depending on the degree of the potential charges. Victims are not registered, neither are convicts after conviction, since as Article 38 of the Criminal Records Act states the objective of DNA profile registration is exclusively the identification or exclusion of suspects charged with specific crimes during criminal procedures. According to Article 39 Section (1) of the Criminal Records Act the data of those persons have to be registered, who are charged with a crime

- a) that is to be punished with minimum five years imprisonment, or
- b) that can be related to international criminality,
- c) that is violent and is directed against sexual morals,
- d) that is directed against minors,
- e) committed in a serial or organized manner,
- f) in connection with narcotic drugs, or substances that amount to narcotic drugs, if the crime is to be punished with more than two years imprisonment,
- g) in connection with counterfeiting of money or securities,
- h) perpetrated by force of arms, or
- i) due to the omission of reporting of crimes against the state, acts of terrorism, violation of a duty based on

<sup>21</sup> In original language: 1992. évi LXIII. törvény a személyes adatok védelméről és a közérdekű adatok nyilvánosságáról, available at [http://net.jogtar.hu/jr/gen/hjegy\\_doc.cgi?docid=99200063.TV&jab=1](http://net.jogtar.hu/jr/gen/hjegy_doc.cgi?docid=99200063.TV&jab=1), adopted on 17 November, 1992, entering into force on 1 May, 1993.

<sup>22</sup> Article 43 Section (2) of the Criminal Records Act.

<sup>23</sup> Article 43 Sections (3)-(5) of the Criminal Records Act.

<sup>24</sup> Article 43 Section (2) of the Criminal Records Act.

international law, misuse of the application of nuclear energy, money laundering, service crimes, or due to the well-grounded suspicion of preparation to terrorist acts, except for criminal procedures initiated on the ground of private accusation, independently of whether the public prosecutor has taken over the representation of the charges or not.

Furthermore DNA profiles gained from the remainders of the material found at the scene of the crime also have to be registered in the DNA registry.<sup>25</sup>

Samples may also be taken from people under 14 or 18 years of age, or from mentally disabled persons.

## 5. ACCESS TO DATA AND SAMPLES

According to Article 40 of the Criminal Records Act the DNA profile registry contains personal data such as family and surname(s), in applicable their maiden name, sex, place and date of birth, mother's maiden name, ID number, previous surnames(s) and family name, nationality and domicile; the denomination of the crime or crimes, and their classification according to the Criminal Code; the location and time of the crime or crimes; the name of the responsible investigation authority, the registration number of the criminal case; the identification code related to the registered individual; the DNA profile and the related identification code.

When identifying persons who have the right to request data, the Criminal Records Act and the Data Protection

Act may give us guidance. The former lists the state organs that may request data, whereas the latter is applicable to the suspects' right to ask for information and data.

According to Article 46 of the Criminal Records Act the following entities may request data from the DNA profile registry: the judiciary, the public prosecutor's office and investigation authorities; national security services. Also foreign entities may request data according to the laws on legal aid, international treaties, and other international obligations. These institutions include foreign investigation authorities, foreign judiciary, public prosecutor's office, and international judicial and crime prosecution organs. The National Criminal Cooperation Center, or other Hungarian organs that are entitled by an international treaty to the transmission of data to foreign entities may also process data requests from the forensic biobank.

Article 46 Section (2) of the Criminal Records Act provides that exclusively data that are absolutely necessary for the identification of the person in question can be transferred to the above listed entities. These data must be limited to personal data, crimes the person is charged with, location and time of the crime committed, the investigating authority, and the case number.

The Data Protection Act provides in Article 11 that any data subject may request on the one hand confirmation as to whether or not data relating to him or her are being processed, and on the other the rectification or erasure of

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<sup>25</sup> Article 39 Section (1) of the Criminal Records Act.

his or her personal data, with the exception of those processed by order of legal regulation. Data in forensic biobanks naturally amount as an exception from the general rule.

Article 12 of the Data Protection Act provides that the person concerned may ask the data manager to provide information as to the data relating to him or her, including data processed, the purpose, grounds and duration of processing, the name and address (seat) of the data processor and its activities relating to data management, the recipients of his or her data and the purpose for which they are or had been transferred.

Cross-linking of the biobank with another database is not allowed.

## 6. STORAGE

According to Article 45 of the Criminal Records Act data in the forensic biobank have to be registered until the following dates:

- a) persons against whom criminal proceedings have been initiated on the grounds of a well-founded suspicion of a crime listed by the above mentioned Article 39 of the same Act, i.e. persons who have to be registered in the forensic biobank by the force of law;
  - aa) in case of conviction, until 20 years from the exemption from the disadvantages attached to the conviction;
  - ab) until the deadline of the prescription of punishability of the crime, in case of forced medical treatment, probation, or ordering education in a reformatory institution;
- b) until the day of the sentence the becoming non-appealable, if the

investigation or the criminal proceeding has been terminated;

- c) until the deadline of the prescription of punishability of the crime in case of a DNA profile established from sample remainders found at the premises of a crime.

## 7. SUPERVISION

According to Article 47 of the Criminal Records Act in order to supervise the legality of data processing, the Minister responsible for personal data and address registration, the data protection ombudsman, or their representatives, and the responsible public prosecutor may have access to the forensic DNA bank.

## 8. CONSTITUTIONAL REVIEW

Although everything described above is still good law in Hungary, due to a decision of the Hungarian Constitutional Court (hereinafter referred to as "HCC") the landscape of forensic biobank-related legislation will considerably change in the future. On 25 November, 2008 the HCC declared certain parts of the Criminal Records Act and of Decree 8/2000 (II. 16.) as of June 30, 2009 unconstitutional and therefore null and void.

The Court first gave a definition of forensic genetic databases, and then went into the constitutional analysis of the merits. Forensic databases are comprehensive, interlinked, officially recognized and structured databases containing especially large numbers of personal and sensitive data of suspects and convicts, which may be used for criminal purposes in the widest sense of the word (substantive

criminal law, crime prosecution, intelligence) and which simultaneously have an important role in international criminal cooperation and in the mutual exchange of information. Forensic databanks, so the Court, also have a crucial role in areas outside the criminal law field, first and foremost as a benchmark for the possible limitations of fundamental rights. The HCC mentioned human dignity and rights derived therefrom, some of which are named in the Constitution, and some of which are not. These rights include the right to self-determination, the right to privacy and data protection, and the fact that the consequences of criminal behavior shall not be unlimited. Rehabilitation is also derived from human dignity, and it is not only the interest of the perpetrator, but also that of society as a whole.

The processing of data in a forensic database is in itself a violation of fundamental rights. The Hungarian Constitution's Article 54 Section (1) on human dignity and Article 59 on data protection are to be invoked in this context. In its previous case-law, the HCC emphasized that everyone shall have the right to dispose of his or her own data. Exceptionally authorities may be exempted from this rule, but such a departure from the general right to data protection must comply with Article 8 of the Constitution, i.e. the limitation must be prescribed by law, and the essential core of the right in question must not be infringed in order for the limitation to be constitutional. Necessity and proportionality must be evaluated strictly, i.e. these constitutional tests do not automatically permit rights restrictions in the name of the public interest.

The Constitutional Court held that the factors developed for the storage of forensic data are promiscuous, disproportionately long, which in itself endangers the principle of data security and lead to the establishment of a global database operating without proper data protection guarantees. The scope of persons who may request data from the forensic database is also disproportionately wide, and therefore in violation of the Constitution. These persons authorized may request data irrespective of the objective of data handling, the flow of data often becomes obscure.

The HCC also found the fact unconstitutional that data are universally kept much longer than the statute of limitation for the disadvantages attached to conviction expires. The justices emphasized that rehabilitation contributes to their employment opportunities, and helps avoiding recidivism. According to the HCC the fact that data are not deleted from a forensic database on the day the convict is exempted from the disadvantages attached to the conviction, is not in line with the objectives of criminal law as the ultimate tool in case of violations of the law, and is in violation of human dignity. It also creates unjustified inequality among persons who are supposed to be presumed innocent. Being convicted or being convicted and later exempted from the disadvantages attached to the conviction is not a protected characteristic mentioned in the equality clause, i.e. Article 70/A of the Hungarian Constitution, but according to the wording of the provision the Republic of Hungary has to respect the human rights and civil rights of all persons without discrimination on the basis of a num-

ber of specifically named grounds, such as for example race, color, gender, or on the basis of “any other grounds whatsoever.” It was on the basis of this latter provision that the HCC determined inequality among persons presumed to be innocent. The Constitutional Court acknowledged that there might be a need in case of certain serious offences to store data beyond the date of exemption from the disadvantages attached to the conviction, however the indiscriminate universal prolongation of this rule created an unnecessary and disproportionate distinction between persons who shall be seen as innocent.

The Court criticized Articles 5-6 of Decree 8/2000 for regulating coercive sample taking, which is a clear violation of fundamental rights and therefore should not be regulated in a lower legal instrument. The HCC acknowledged that the Decree is a piece of delegated legislation, since there is also reference to this issue in the Criminal Records Act, but still the Court found there was an unjustified repetition of the rule on coercive sample taking thereby degrading the provision to lower level legislation. Further the Court noted there was a considerable risk that at a certain point in time the Act is modified, and the intrusive action of sample taking will indeed only be regulated by a Decree.

Justices András Bragyova, András Holló and Péter Kovács wrote separate dissenting opinions. In relation to the forensic use of the DNA Judge Bragyova disagreed with the holding that the repetition of coercive sample tak-

ing in a lower piece of legislation was unconstitutional. According to Judge Kovács the length of storage was in itself not unconstitutional, however long, but the problem was that the law was not sufficiently differentiating between the various types of crimes.

In the meanwhile the Hungarian Ministry of Justice and Law Enforcement has drafted a new bill remedying the above constitutional problems.<sup>26</sup>

## 9. PUBLIC DEBATE

A public debate has not taken place on forensic biobanks. Although there have been some attempts at the negotiations of a comprehensive biobank law to reopen the debate around forensic biobanks as well, finally those scientists prevailed who only wished biobanks for research and therapeutic purposes to be included into the Biobank Act.

The lack of a debate can alternatively be explained by the fact – and this is the view represented by forensic experts – that forensic institutions did not want to release many pieces of information about criminal investigation techniques.

Recently, a debate arose over the visa-waiver program between the United States of America and Hungary, when on 20 October, 2008 President of the Republic László Sólyom did not promulgate, but returned a bill on sharing criminal data to the Parliament for reconsideration. The President claimed that there was a considerable constitutional risk of potential human rights violations, as the agreement

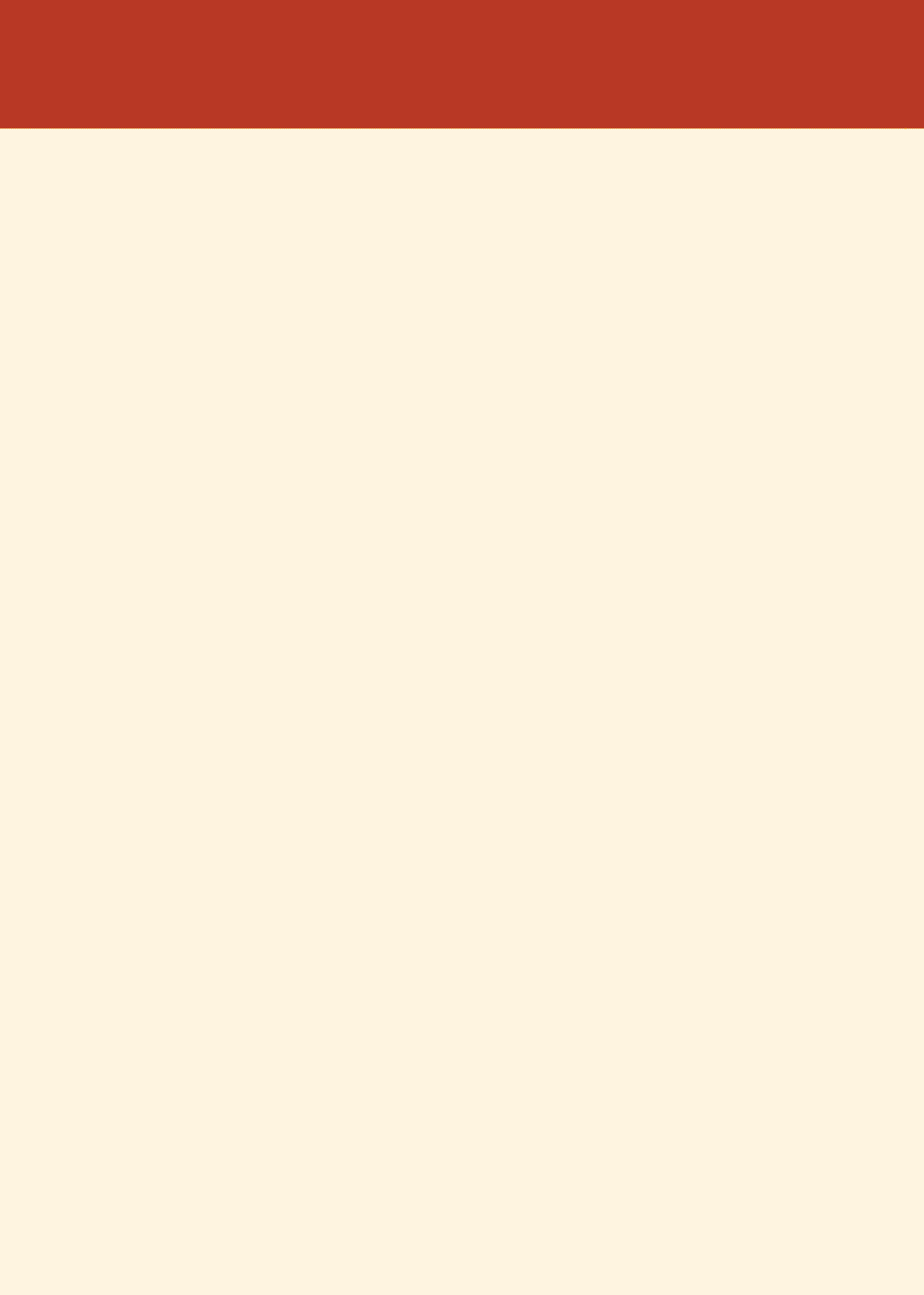
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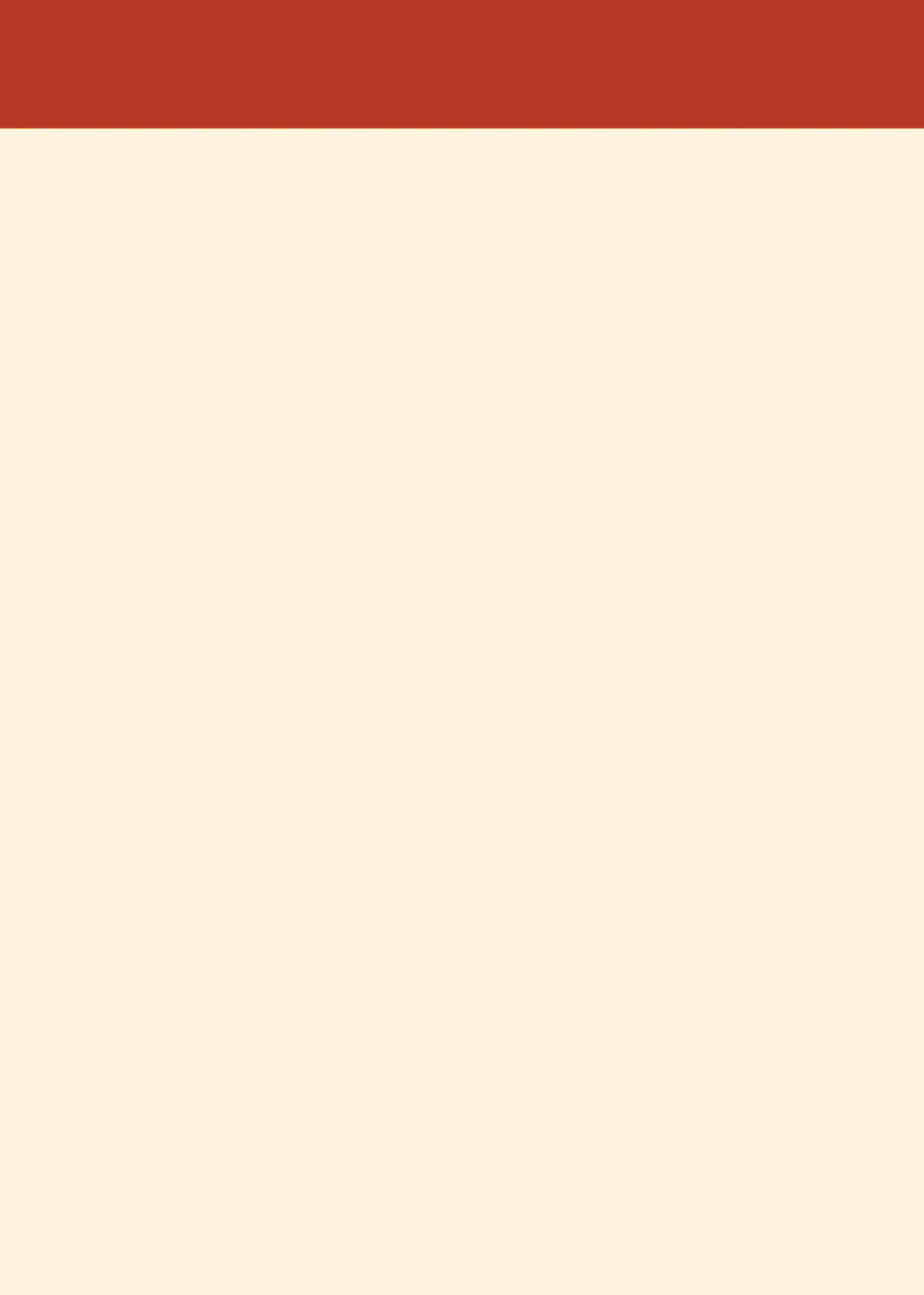
<sup>26</sup> [http://irm.gov.hu/download/bnyt\\_eloterjesztes\\_03.02.doc/bnyt\\_eloterjesztes\\_03.02.doc](http://irm.gov.hu/download/bnyt_eloterjesztes_03.02.doc/bnyt_eloterjesztes_03.02.doc)



between the US and Hungary authorized keeping of a register of fingerprints and DNA taken from various groups of persons, which the US could then access with the Hungarian pieces of legislation in line. The register would have included and made available information on victims, and persons present at a crime scene, and not only suspects and convicts. The President

asked the legislative primarily to reconsider the Criminal Records Act as a background piece of legislation of the agreement, which ultimately happened by the HCC in the above described decision. The EU Data Privacy Ombudsman Peter Hustinx and the Hungarian Data Privacy Ombudsman András Jóri also protested against the original version of the agreement.







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