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The legal regulation of biobanks: National report: Romania

Item Type	Working paper
Authors	Sándor, Judit;Demény, Enikő;Bárd, Petra
Publisher	Center for Ethics and Law in Biomedicine
Download date	2024-10-07 17:20:03
Link to Item	http://hdl.handle.net/20.500.14018/6661

No. 9
CELAB PAPER SERIES

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THE LEGAL REGULATION
OF BIOBANKS

National Report:
Romania



CENTER FOR ETHICS AND LAW
IN BIOMEDICINE





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© September 2009

Center for Ethics and Law in Biomedicine (CELAB)

ISSN 2074-4498

ISBN 978-963-9776-56-2

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Design and layout: Zsolt Sándor

Printed in Hungary by AduPrint Kft.

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



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

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

Italy, Latvia, Lithuania, Malta, Poland, Romania, the Slovak Republic, and Slovenia. The present booklet is the first one in the series of country reports prepared by CELAB.

In the framework of the research, Enikő Demény has conducted several interviews with Romanian experts in the field and a related questionnaire has been filled out. A number of national experts contributed to our research by explaining the Romanian regulation and practice, making valuable comments, or helping with the translations. We are especially grateful to Georgeta Basarabescu, Director of the Romanian National Supervisory Authority for Personal Data Processing; Simona Zanfir, Counselor at the Legal and Communication Department of the Romanian National Supervisory Authority for Personal Data Processing; Dr. Ioana Berindan-Neagoe, Associate Professor at the University of Medicine and Pharmacy “Iuliu Hațieganu”, and Head of Functional Genomics Department, Cancer Institute “Ion Chiricuță”, Cluj-Napoca; Liana Policiuc, Legal Counselor at the Cancer Institute “Ion Chiricuță”, Cluj-Napoca; Dr. Rosana

Turcu, Regional Coordinator for Bucharest, National Transplant Agency, Csongor Kuti, Legal Counselor, Târgu-Mureş and Mariana Aurelia Bistriceanu, Legal Counselor at the Ministry of Administration and Internal Affairs.

The present booklet summarizes the regulatory framework of biobanks in Romania and focuses on the collection and analysis of legislation and regulation regarding the establishment, management and functioning of classical, population and forensic biobanks. As the legal regulation of classical and

population biobanks does not show variations, these two will be discussed jointly in Part I, whereas forensic biobanks invoking legal issues of different nature will be covered separately in Part II. The present analysis does not cover either the international standards, or the pieces of European Union law, but it should be borne in mind that they are binding on Romania being a European Union Member State.

Budapest, 1 September 2009

CLASSICAL AND POPULATION BIOBANKS

1. DEFINITION OF BIOBANKS

Like in the majority of the Member States in the region, there is no overall, all-encompassing definition of research and diagnostic biobanks in Romania.

Law No. 95/2006 on Health Reform makes reference to tissue and cell banks. According to Article 148 Section (4) of this Law those human tissues and cells collected for therapeutic purposes that are not immediately used for transplantation shall be stored in tissue and cells banks accredited by the National Transplant Agency.¹

A definition of tissue and cell banks is explicitly given in Article 1 (m) of Annex to Decree No. 1242/2007 of the Ministry of Public Health on setting the standards of selection and evaluation of tissue and cell donors. A tissue and cell bank is defined as a specialized and individualized medical unit, a section of a hospital or other public or private healthcare institution that is accredited for the collection, processing, biological control, validation, conservation, storage and distribution of human tissues and cells.

Romania has currently 30 accredited tissue and cell banks (4 skin-, 3 bones-, 1 cardiac-, 2 pancreatic cells-, 17 reproductive cells-, and 3 stem cells-banks) and 42 accredited institutions as users of tissue and cell banks (9 skin-, 8 bones-, 2 cardiac-, 4 cornea-, 2 pancreatic cell-, and 17 reproductive cell-banks).¹ These are all institutions that, with one exception, have been accredited in a first round until 1st of July 2010, for therapeutic purposes, mainly for transplantation.³

The legal instruments related to tissue and cell banks mention in their title only the therapeutic purpose of such collections.⁴ However, Decree No. 1763/2007 that set up the details of the organizing and functioning of these banks mentions research as the other possible objective of the collection, by stating that the information registered in tissue and cell banks have to include “the consent/authorization, including the purpose/purposes (therapeutic and/or research) for which the tissues and cells shall be used for.”⁵ Therefore the human biological materials collected and stored in the accredited tissue and cells banks

¹ Law No. 95/2006, Chapter VI, Article 148 Section (4).

² Accredited by Ministry of Health’s Decree No. 1225/2008, Article 2-3. After the publication of this Decree 8 more institutions have got accreditation.

³ *Id.*, Article 5.

⁴ See the enumeration of these legal instruments in Section 2 of this Report.

⁵ Annex to Decree No. 1763/2007, Annex IV, Article 2.4, Point (a). Article 2.5 states the similar requirement in the case of donation of reproductive cells among partners. In this case too the scope of the donation (reproductive and/or research) has to be specified.

can be used not only for therapeutic purposes, but for research too, if research has been mentioned as purpose of the donation, and this information is registered in the biobank.⁶

Apart of the accredited tissue and cell banks, there are numerous collections of stored human tissues and cells in various hospitals and research institutes/universities.⁷ The human biological materials and the related personal data collected in such settings can be used only for biomedical research purposes, in accordance with the legal and ethical rules applicable to biomedical research and data protection.⁸

2. RELEVANT LAWS

Currently there is no specific law on classical biobanks in Romania, but the legal rules are fragmented and dispersed in various norms. There were no cases decided by the judiciary applicable to classical biobanks yet.

The enumeration of domestic legal instruments in this section will follow

the hierarchy of norms in the Romanian legal system. Accordingly the list of laws will be followed by the decrees of the respective ministries, and than by bylaws and codes of conduct.

Laws applicable to biobanks:

Laws on tissue and cell donation:

- Law No. 95/2006 on Reform on Public Health – Title VI: The Storage and Transplant of Organs, Tissues and Human Cells for Therapeutic Purposes, with Annexes I-XIII, and the Methodological Norms for the application of the Law;⁹
- Law No. 588/2004 for the approval of Governmental Ordinance No. 79/2004 on the Establishment of the National Transplant Agency;¹⁰
- Law No. 104/2003 on the Manipulation of Human Cadavers and on the Collection of Organs and Tissues of Cadavers for Transplants;¹¹

Laws on data protection:

- Law No. 677/2001 on the Protection of Individuals Concerning the Pro-

⁶ This information has been also confirmed by Rosana Turcu, Regional Coordinator at the National Transplant Agency.

⁷ For example the collection of tumor tissues and cells at the Cancer Institute “Ion Chiricuță”, Cluj (The functional genomics, proteomics and experimental pathology ‘biobank’), or the collection of Victor Babeș Național Institute for Pathology and Biomedical Research, Bucharest.

⁸ Biobank questionnaire, filled by Dr. Ioana Berindan-Neagoe, Cancer Institute “Ion Chiricuță”, Cluj.

⁹ In original language: Legea nr. 95 din 14 aprilie 2006 privind reforma în domeniul sănătății, Capitolul VI, cu Anexele I-XIII, și normele metodologice de aplicare a Capitolului VI, available at http://www.cdep.ro/proiecte/2006/000/40/3/leg_pl043_06.pdf or at http://www.ms.ro/fisiere/legislatie/73_93_LEGEA%20%20Nr%2095.doc, adopted on 14 April 2006, entered into force on 1 May 2006, amended later, the latest version entered into force on 15 August 2008.

¹⁰ In original language: Legea nr. 588 din 15 decembrie 2004 pentru adoptarea Ordonanței Guvernamentale nr. 79 din 19 august 2004, pentru înființarea Agenției Naționale de Transplant, available at http://www.cdep.ro/proiecte/2004/600/70/3/leg_pl673_04.pdf adopted on 15 December 2004, entering into force on 21 Decembrie 2004.

¹¹ In original language: Legea nr. 104 din 27 martie 2003 privind manipularea cadavrelor umane și prelevarea organelor și țesuturilor de la cadavre în vederea transplantului, available at http://www.cdep.ro/proiecte/2002/300/50/7/leg_pl357_02.pdf, adopted on 27 March 2003, entering into force on 3 April 2003.

cessing of Personal Data and Free Movement of Such Data;¹²

- Law No. 682/2001 on the Ratification of the Council of Europe Convention for the Protection of Individuals with regard to Automatic Processing of Personal Data (Convention No.108);¹³
- Law No. 102 /2005 on the Establishment, Organization and Functioning of the National Supervisory Authority for Personal Data Processing,¹⁴

Laws on research:

- Law No. 206/2004 on Good Practice in Research, Technological Development and Innovation;¹⁵
- Law No. 324/2003 on the Approval of Governmental Order No. 57/2002 on Scientific Research and Technological Development;¹⁶

Laws on human rights:

- Law No. 17/2001 on the Ratification of the Convention for the Protection of Human Rights and Dignity of the Human Being with Regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine, signed at Oviedo on 4 April 1997, and its Additional Protocol, signed in Paris at 12 January 1998;¹⁷
- Law No. 46/2003 on Patients' Rights;¹⁸

Other applicable laws:

- The Penal Code of Romania.¹⁹

Decrees:

- Decree No. 1225/2008 of the Ministry of Public Health on the modification

¹² In original language: Legea nr. 677 din 21 noiembrie 2001 pentru protecția persoanelor cu privire la prelucrarea datelor cu caracter personal și libera circulație a acestor date, available at http://www.cdep.ro/pls/legis/legis_pck.htm_act_text?id=30822, adopted on 21 November 2001, entering into force on 12 December 2001.

¹³ In original language: Legea nr. 682 din 28 noiembrie 2001 privind ratificarea Convenției pentru protecția persoanelor față de prelucrarea automatizată a datelor cu caracter personal, adoptată la Strasbourg la 28 ianuarie 1981, available at http://www.igpf.ro/prot_date/lg_682_2001.pdf, adopted on 28 November 2001, entering into force on 21 December 2001.

¹⁴ In original language: Legea nr. 102 din 3 mai 2005 privind înființarea, organizarea și funcționarea Autorității Naționale de Supraveghere a Prelucrării Datelor cu Caracter Personal http://www.cdep.ro/proiecte/2004/700/40/7/leg_pl747_04.pdf adopted on 3 May 2005, entering into force on 9 May 2005.

¹⁵ In original language Legea nr. 206 din 27 mai 2004 privind buna conduită în cercetarea științifică, dezvoltarea tehnologică și inovare, available at http://www.cdep.ro/proiecte/2003/400/40/2/leg_pl442_03.pdf, adopted on 27 May 2004, entering into force on 4 June 2004.

¹⁶ In original language: Legea nr. 324 din 8 iulie 2003 pentru aprobarea Ordonanței Guvernului nr. 57/2002 privind cercetarea științifică și dezvoltarea tehnologică, available at http://www.cdep.ro/pls/legis/legis_pck.htm_act_text?id=37578, adopted on 8 July 2003, entering into force on 16 July 2003.

¹⁷ In original language: Legea nr. 17 din 22 februarie 2001 privind ratificarea Convenției europene pentru protecția drepturilor omului și a demnității ființei umane față de aplicațiile biologiei și medicinei, Convenției privind drepturile omului și biomedicină, semnată la Oviedo la 4 aprilie 1997, și a Protocolului adițional la Convenția europeană pentru protecția drepturilor omului și a demnității ființei umane față de aplicațiile biologiei și medicinei, referitor la interzicerea clonării ființelor umane, semnat la Paris la 12 ianuarie 1998, adopted on 17 February 2001, entering into force on 28 February 2001.

¹⁸ In original language: Legea nr. 46 din 21 ianuarie 2003 privind drepturile pacientului, available at http://www.cdep.ro/pls/legis/legis_pck.htm_act_text?id=39946, adopted on 21 January 2003, entering into force on 29 January 2003.

¹⁹ In original language: Codul Penal al României, available at <http://www.anp-just.ro/interna/Codul%20Penal.pdf>, adopted on 1968, the revised version of the cod entering into force on 28 March, 2008.

and complementation of Ministry of Public Health's Decree No. 722/2006 on the accreditation of health care institutes that are authorized to carry out activities of human tissue banks, as well as users of human tissue banks for therapeutic purposes;²⁰

- Decree No. 1242/2007 of the Ministry of Public Health on the approval of standards for the selection and evaluation of tissue and cell donors, the alert systems and emergency procedures, the qualification of the personnel of tissue and cell banks, the quality, import and export of human tissues and cells, and the relationships between tissue and cell banks and third parties;²¹
- Decree No. 1763/2007 of the Ministry of Public Health on the technical requirements for donation, sampling, testing, processing, preservation, dis-

tribution, coding, the traceability rules of tissues and cells of human origin used for therapeutic purposes, and notification of serious adverse incidents and serious adverse reactions occurring during their processing;²²

- Decree No. 183/2005 of the Ministry of Public Health on the organization and functioning of the National Transplant Agency;²³
- Decree No. 3609/2008 of the Ministry of Education, Research and Youth on the modification and complementation of Decree No. 400/2007 on the approval of the constitution of the National Ethics Council for Scientific Research, Technological Development and Innovation, of its Secretariat, of the Ethics Committees with permanent statute, as well as on the approval of the rules for

²⁰ In original language: Ordin nr. 1225 din 1 iulie 2008 pentru modificarea și completarea Ordinului Ministerului Sănătății Publice nr. 722/2006 privind acreditarea unităților sanitare care pot efectua activități de bănci și țesuturi umane, respectiv de utilizator de țesuturi și/sau celule umane în scop terapeutic, available at http://www.transplant.ro/Lege/Ordin_1225_2008.html, adopted on 1 July 2008, entering into force on 8 July 2008.

²¹ In original language: Ordinul nr. 1242 din 12 iunie 2007 al Ministerului Sănătății Publice pentru aprobarea standardelor privind selecția și evaluarea donatorului de țesuturi și celule, sistemele de alertă și procedurile de urgență, calificarea personalului din băncile de țesuturi și celule, sistemul de calitate, importul și exportul de țesuturi și celule umane, relațiile între băncile de țesuturi și celule și terțe părți, available at [http://www.legestart.ro/Ordin-nr-1242-din-2007-\(MjYzMTY3\).htm](http://www.legestart.ro/Ordin-nr-1242-din-2007-(MjYzMTY3).htm), adopted on 12 June 2007, entering into force on 9 August 2007.

²² In original language: Ordin nr. 1763 din 12 octombrie 2007 al Ministerului Sănătății Publice privind stabilirea cerințelor tehnice pentru donarea, prelevarea, testarea, procesarea, conservarea, distribuirea, codificarea și trasabilitatea țesuturilor și celulelor de origine umană utilizate în scopuri terapeutice, precum și notificarea incidentelor adverse severe și a reacțiilor adverse grave survenite în timpul transplantării lor, available at [http://www.legestart.ro/Ordin-nr-1763-din-2007-\(Mjc4Mjk0\).htm](http://www.legestart.ro/Ordin-nr-1763-din-2007-(Mjc4Mjk0).htm), adopted on 12 October 2007, entering into force on 16 October 2007. The provisions of this Decree are transposing the Directive of the European Parliament and Council 17/2006/EC of 8 February 2006 to implement the Directive of the European Parliament and Council 23/2004/EC on technical requirements for donation, sampling and testing of human tissue and cells, and Directive of the European Parliament and Council 86/2006/EC of 24 October 2006 to implement the Directive of the European Parliament and Council on 23/2004/EC on traceability requirements, notification of serious adverse reactions, serious adverse incidents, some requirements concerning technical coding, processing, preservation, and the distribution of human tissues and cells.

²³ In original language: Ordin nr. 183 din 10 martie 2005 privind organizarea și funcționarea Agenției Naționale de Transplant, available at http://www.transplant.ro/Lege/Ordin_183_2005.html, adopted on 10 March 2005, entering into force on 18 March 2005.

organizing and functioning of the National Ethics Council for Scientific Research, Technological Development and Innovation;²⁴

- Government Order No. 1449/2005 on the organizing and functioning of the National Authority for Scientific Research;²⁵
- Government Order No. 57/2002 on scientific research and technological development.²⁶

Bylaws, cods of conduct:

- Decision No. 11/2009 of the National Supervisory Authority for Personal Data Processing regarding the establishment of the categories of personal data operations susceptible to present special risks for the rights and liberties of persons;²⁷
- Decision No. 10/2009 of the National Supervisory Authority for Personal

Data Processing regarding the establishment of an authorization model for the transfer of personal data abroad based on the provisions of Article 29 Section (4) of the Law no. 677/2001 for the protection of persons regarding the processing of personal data and the free movement of such data;²⁸

- Decision No. 101/2008 of the National Supervisory Authority for Personal Data Processing for the issuing procedure of the authorization for personal data processing regarding the health state, in the conditions of Article 9 Sections (3) and (4) of the Law No. 677/2001 with regard to the personal data processing and on the free movement of such data;²⁹
- Decision No. 95/2008 of the National Supervisory Authority for Personal Data Processing regarding the establishment of the standard type notifi-

²⁴ In original language: Ordinul nr. 3609 din 31 martie 2008 al Ministerului Educației, Cercetării și Tinerețului pentru modificarea și completarea Ordinului nr. 400/2007 pentru aprobarea componenței Consiliului Național de Etică a Cercetării Științifice, Dezvoltării Technologice și Inovării, a secretariatului acestuia, a Comisiilor permanente, precum și a Regulamentului său de organizare și funcționare, cu modificările și completările ulterioare, adopted on 31 March 2008.

²⁵ In original language: Hotărârea Guvernului nr. 1449 din 17 noiembrie 2005 privind organizarea și funcționarea Autorității Naționale pentru Cercetarea Științifică, available at http://www.cdep.ro/pls/legis/legis_pck.frame, adopted on 17 November 2005, entering into force on 7 December 2005.

²⁶ In original language: Ordonanța Guvernamentală nr. 57 din 16 august 2002 privind cercetarea științifică și dezvoltarea tehnologică, available in up-dated version at <http://www.mct.ro/index.php?action=view&idcat=23>, adopted on 16 August 2002, entering into force on 30 August 2002.

²⁷ In original language: Decizia nr. 11 din 5 martie 2009 a Autorității Naționale de Supraveghere a Prelucrării Datelor cu Caracter Personal privind stabilirea categoriilor de operațiuni de prelucrare a datelor cu caracter personal, susceptibile de a prezenta riscuri speciale pentru drepturile și libertățile persoanelor, available at <http://www.dataprotection.ro/?page=publicated&lang=ro> adopted on 5 March 2009, entering into force on 12 March 2009.

²⁸ In original language: Decizia nr. 10 din 2 martie 2009 privind stabilirea unui model de autorizație pentru transferul în străinătate al datelor cu caracter personal în baza articolului 29 alineat (4) din Legea nr. 677/2001 pentru protecția persoanelor cu privire la prelucrarea datelor cu caracter personal și libera circulație a acestor date, available at <http://www.dataprotection.ro/?page=publicated&lang=ro> adopted on 2 March 2009, entering into force on 10 March 2009.

²⁹ In original language: Decizia No. 101 din 29 decembrie 2008 a Autorității Naționale de Supraveghere a Prelucrării Datelor cu Caracter Personal privind starea de sănătate, în condițiile articolului 9 alineat (3) și (4) din Legea nr. 677/2001 pentru protecția persoanelor cu privire la prelucrarea datelor cu caracter personal și libera circulație a acestor date, available at <http://www.dataprotection.ro/?page=publicated&lang=ro> adopted on 29 December 2008, entering into force on 1 February 2009.

cation form ruled by the Law No. 677/2001 for the protection of persons regarding the processing of personal data and the free movement of such data;³⁰

- Annex No. 2 of Decision No. 3/2005 of the Romanian College of Physicians on the adoption of the statute and the deontological code of the physician, Section: "Rules regarding human medical research."³¹

The tissue and cell sample collection is considered in each case as a donation act and apart of the legal provisions a number of ethical guidelines shall be observed in case of such "donation." Cells and tissues shall be recovered in a manner that respects the family's expectation about how they will be used; tissue and cell resources shall be shared on fair and compensatory terms with other tissue banks and the public, to avoid shortages in their availability; tissues and cells shall be treated and distributed in ways that maximize their usefulness to the patient community; the distribution of tissues and cells in a discriminatory manner shall be avoided; donation and recovery activities shall be done in cooperation with health care professionals in a manner that will not diminish public confidence in donation;

the public perception of the advertisements shall be carefully considered and the use of terms that could cheapen the concept of the "gift of life" shall be avoided; accurate information shall be provided, unfounded or misleading statements shall be avoided; community support for donation shall be emphasized, and advertisements that undermine community support of tissue donation shall be avoided; and finally any leaking information concerning patient's confidentiality shall be avoided.³²

According to Article 28 of Law No. 677/201 the professional associations have the obligation to elaborate and submit for approval, to the supervisory authority, codes of conduct that contain adequate rules for the protection of the rights of persons whose personal data may be processed by the members of the associations. The rules of conduct must contain measures and procedures able to ensure satisfactory protection, taking into account the nature of the data that may be processed. The supervisory authority may impose other specific measures and procedures for the period of time during which the rules of conduct are not adopted.

Research activities carried out with human biological materials and related

³⁰ In original language: Decizia nr. 95 din 11 decembrie 2008 a Autorității Naționale de Supraveghere a Prelucrării Datelor cu Caracter Personal privind stabilirea formularului tipizat al notificărilor prevăzute de Legea nr. 677/2001 pentru protecția persoanelor cu privire la prelucrarea datelor cu caracter personal și libera circulație a acestor date, available at <http://www.dataprotection.ro/?page=publicated&lang=ro>, adopted on 11 December 2008, entering into force on 1 March 2009.

³¹ In original language: Anexa nr. 2, Codul de deontologie medicală la Decisia nr. 3 din 25 martie 2005 emisă de Colegiul Medicilor din România privind adoptarea statutului și a Codului de deontologie medicală al Colegiului Medicilor din România, available at <http://www.cmb.ro/legislatie/codulDeontologic/cod.pdf> adopted on 25 March 2005, entering into force on 18 May 2008.

³² These ethical principles have been presented in the lecture of Dr. Berindan-Neagoe, at the Tiss.Eu project workshop, 6-8 April, 2009, Budapest.

personal data fall under the competence of the National Research Ethics Council. The Council is the Romanian Government's advisory body on ethical issues raised by scientific and technological advances in research activities and it monitors the applications of moral and professional codes in research activities.³³ The National Research Ethics Council's work is carried out within permanent or temporary bodies.³⁴ The ethical codes for the domains of sciences have to be elaborated by the Permanent Committees, and have to be submitted by the National Ethics Council for approval to the National Agency for Scientific Research.³⁵ In the elaboration of ethical codes the international norms to which Romania is part shall be respected.³⁶

There is no specific law or regulation on the research with human biological materials, but the legal and ethical norms on medical research and on research on human subjects shall be applied.³⁷

Human medical research has to correspond to certain expectations, which are set up in the Annex No. 2 of Decision No. 3/2005 of the Romanian College of Physicians. According to Article 88 of this

Decision research on human beings shall be carried out with the observance of all conditions set up in this respect in the international conventions and declarations adopted in Romania. In this context it shall be mentioned that Romania has ratified in 2001 the Convention for the Protection of Human Rights and Dignity of the Human Being with Regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine and its Additional Protocol.³⁸

According to Article 91 and 92 of the above mentioned Decision in human medical research the well-being of an individual shall be, generally, above the interests of society and science, and human medical research for medical progress must be permitted on human subjects only as a last resort. The research must be conducted according to scientific data and according to other relevant information resources, including for example the information from animal experiments, whenever possible. The declared purpose for human medical research shall be to improve prophylactic methods, diagnosis and treatments as well as understanding the etiology and pathogenesis of a disease.³⁹

³³ The National Research Ethics Council was enacted in the good practice Law No. 206/2004 and the Orders 400/2007 and 3609/2008 of the Ministry of Education, Research and Youth. The National Research Ethics Council role shall be seen in the context of other advisory and regulatory bodies in the regulatory and advisory framework for research (e.g. Consultative Council from National Authority for Scientific Research). The National Research Ethics Council's roles are to express opinions and suggest solutions, also for the purpose of preparing legislative acts; to address the ethical and legal problems that may emerge as a result of the progress of research; to promote the drawing up of codes of conduct for practitioners operating in the various research sectors concerned and to encourage the communication with general public, to act as an expert body working towards the resolution of ethical issues relating to research. See Law No. 206/2004, Article 7.

³⁴ The National Research Ethics Council has three permanent Commissions on a) Socio-humanistic sciences; b) Life Sciences; c) Technical sciences. Decree No. 3609/2008, Annex 2, Article 12.

³⁵ *Id.*, Article 18.

³⁶ Law No. 206/2004, Article 13.

³⁷ Information confirmed by Rosana Turcu, from the National Transplant Agency.

³⁸ See Law No. 17/2001.

³⁹ Annex No. 2 of Decision No. 3/2005 of the Romanian College of Physicians on the adoption of the statute and the deontological code of the physician, Section: "Rules regarding human medical research", Article 93.

Human medical research is conditioned on the cumulative fulfillment of the following provisions: there is no alternative method to human medical research, with comparable efficiency; the risks for a person are proportional with the potential research benefits; the research project was approved by a competent authority (an ethical commission) after an independent evaluation of its pertinent object and after a pluri-disciplinary ethical examination of its acceptability; the human research subject is informed about his or her rights and about the guarantees of his or her protection; the human research subject gave her written consent.⁴⁰ The research protocol shall be evaluated by an independent ethics committee. The ethics committee shall be informed about the course of research and has the right to monitor the ongoing research.⁴¹

Research units and research institutes are responsible for the observance of ethical norms and values and shall establish for this purpose ethical committees in addition to the existing scientific or administrative committees.⁴² During the ethical evaluation process of research projects the evaluation committees shall obligatory verify the observance of the applicable national and international ethical norms, as well as that of the general ethical norms applicable to the protection of human subjects, to the protection of animals, including transgenic animals and human

primates and to the protection of environment. For the protection of human subjects the following issues have to be obligatory verified:

- the use of human embryos, as well as of other human biological materials,
- the use of personal data in case of biobanks, including genebanks,
- the use for clinical trials of the following categories of human subjects: persons without capacity to consent, especially children, pregnant women, healthy volunteers,
- the protection of personal data.⁴³

3. ESTABLISHMENT AND MANAGEMENT OF BIOBANKS

According to Law No. 95/2006 on Reform on Public Health, the human tissues and cells collected for therapeutic purposes that are not immediately used for transplant shall be stored in tissue and cells banks accredited by the National Transplant Agency.⁴⁴ According to Article 5 Section (2) of Decree No. 1242/2007 the identification, reception, processing, storage, labeling, conservation, documentation, packing and distribution of human tissues and cells shall be done with the observance of the relevant EU legislation in force.

The accreditation for biobanks is issued through a Decree of the Ministry of Public Health.⁴⁵ The criteria for the accreditation of tissue and cells banks

⁴⁰ *Id.*, Article 94.

⁴¹ *Id.*, Article 95.

⁴² Law No. 206/2004.

⁴³ *Id.*, Article 12.

⁴⁴ Law No. 95/2006, Chapter VI, Article 148 Section (4).

⁴⁵ *Id.*, Article 160 Section (2).

are laid down in the Ministry of Health Decree No. 1763/2007.⁴⁶ Annex IV of the Decree set up the conditions for the donation, collection, and reception of tissues and cells in the tissue and cell banks. Section 1 concerns the donation and collection procedures and provides technical details about the following issues: the identification and consent of the donor, the evaluation of the donor, the procedure of the collection of tissues and cells, the donor's documentation, packaging of the collected materials, labeling of the collected materials, and labeling of the transporting track. Section 2 gives details about the reception of the donated tissues and cells in the biobank. This section addresses the procedures for the verification and testing of the received biological materials and the accompanying documentation and prescribes what information has to be obligatory registered in the biobank at the receipt of donated tissues and cells. The National Transplant Agency and the Health Inspectorate are the authorities that supervise the fulfillment of the conditions set up in Annex IV.⁴⁷

Annex V contains information on the organization and management of tissue and cell banks, on the necessary qualifications of the personal of such banks, on the necessary equipments and materials, on the conditions set up with regard to the location and the necessary documentation for such biobanks, and on quality assurance. Annex VI set up the conditions for the authorization of the processing, storage, distribution and withdrawal of the tissues and cells in biobanks. The protocols for processing these biological

materials have to be developed for each phase by the specialized committees of the Ministry of Public Health and the Romanian College of Physicians, in accordance with relevant EU norms. Annex X specifies the minimum amount of data that has to be registered about the collected biological material in the biobanks and in the institutions that use the biological materials from the biobanks. Annex XI contains the data that has to be included in the unique European Coding System (ECS). Each product stored in a biobank has to be provided with a unique identification number, which will be registered, along with other data, in the ECS.⁴⁸

In case of collection and processing of biological materials and data from deceased persons the relevant provisions of Law No. 104/2003, Law No. 95/2006, and the Methodological Norms for the Application of Chapter VI of Law No. 95/2006 shall be applied. According to Article 2 of Law No. 104/2003 the right to manipulate human cadavers for diagnostic or research purposes belongs to the accredited or authorized anatomical pathology services of hospitals or institutes for forensic medicine, and to the departments of anatomy and pathologic anatomy of public or private human medical universities. Chapter V of the Law refers to the use of human cadavers for educational and scientific purposes and to the collection of tissues and cells from cadavers. The collection and storage of tissues and cells from human cadavers shall be carried out by the regional transplant centers and accredited hospitals.⁴⁹ The accredited and authorized units shall

⁴⁶ Article 7 of the Annex of the Decree No. 1763/2007 makes reference to Annex V on the criteria for the accreditation of tissue and cell banks.

⁴⁷ Decree No. 1763/2007, Annex, Article 5.

⁴⁸ Article 9 of the Methodological Norms for the application of Chapter VI of the Law No. 95/2006.

establish a system of tissue banks for the conservation of tissues.⁵⁰ The protocols on the collection of tissues and cells from deceased donors shall be drafted by the Scientific Council of the National Transplant Agency and have to be approved by the Ministry of Health.⁵¹

Biobanks contain not only human biological materials but personal identification data and health data, too. Therefore the provisions of Law No. 677/2001 shall be applied. The purpose of Law No. 677/2001 is to guarantee and protect the individual's fundamental rights and freedoms, especially the right to personal, family and private life, with regard to the processing of personal data.⁵² The supervisory authority with regard to Law No. 677/2001 is the National Supervisory Authority for Personal Data Processing. This Authority shall monitor and control the legitimacy of all personal data processing.⁵³

According to Article 22 of Law 677/2001 the data controller is obliged to notify the supervisory authority, either personally or through a representative, before initiating any kind of data processing which has a similar or related purpose to previous data processing activities. The notification shall contain the following information:

- a) the name, address or premises of the data controller and of his or her representative, as the case may be;
- b) the purpose(s) of the data processing;
- c) a description of the category/categories of the data subjects and of the data, or the categories of data, that are to be processed;
- d) the recipients or the categories of recipients to whom the data is intended to be disclosed;
- e) the guarantee accompanying the disclosure to a third party;
- f) the manner in which the data subjects are informed of their rights, an estimate date on ending data processing operations and the future destination of the data;
- g) the intended transfers abroad of personal data;
- h) a general description that allows a preliminary assessment of the measures taken in order to ensure data processing security;
- i) mention of any data filing system related to the processing, and of possible relation to other processing or other data recording systems, irrespective of the fact that they are situated on Romanian territory or not;

⁴⁹ Law No. 104/2003, Article 24 Section (1).

⁵⁰ *Id.*, Article 24 Section (3).

⁵¹ Article 2 Section (1) of the Methodological Norms for the application of the provisions of Chapter VI of Law No. 95/2006.

⁵² Law No. 677/2001, Article 1.

⁵³ In order to achieve this purpose, among its other tasks, the Authority issues the standard notification forms and its own registers; receives and analyses the notifications concerning the processing of personal data and informs the data controller on the results of the preliminary control; authorizes personal data processing in the situations set out by law; informs the natural or legal persons that work in this field, directly or through their associative bodies on the need to comply with the obligations and to carry out the procedures set out by this law; keeps and makes publicly accessible the personal data processing register; is consulted when legislative drafts regarding the individual's rights and freedoms are being developed, concerning personal data processing; may draft proposals on the initiation of legislative drafts or amendments to legislative acts already enforced, in the fields linked to the processing of personal data., *Id.*, Article 21.

- j) the reasons that justify the enforcement of the provisions of Articles 11 and 12 Sections (3) or (4), or of Article 13 Sections (5) or (6), in cases that the data processing is performed exclusively for journalistic, literary, artistic or statistical purposes, or for historical or scientific research.⁵⁴

The supervisory authority shall establish the categories of processing operations that may present special risks for the person's rights and freedoms. If on the basis of the notification, the supervisory authority assesses that the data processing may present special risks for the person's rights and freedoms, it shall decide on a preliminary control before the data processing in case begins, and accordingly informs the controller.⁵⁵

According to the National Authority for the Protection of Personal Data's Decision No. 11/2009 Article 1 Section (1) personal data processing operations in connection with the personal data concerning the health state or the sexual life, as well as the genetic and biometric data (including data processed for scientific purposes), are categories of personal data processing operations susceptible to presenting special risks for the individual's rights and liberties. In such cases processing operations impose the performance of a prior control and the operators shall

notify the National Supervisory Authority for Personal Data Processing with regard to all the personal data processing operations, from at least 30 calendar days prior to starting the processing.⁵⁶ The operators have to fill the form "Notification for Personal Data Processing", incorporated into Decision No. 95/2008.⁵⁷

Decision No. 101/2008 refers to the processing of personal data regarding the health state in cases when the persons concerned did not give their consent to data processing, or the processing of their personal data serves the interests of other persons. According to Article 1 Section (1) of the Decision, processing the personal data regarding the health state, with the purpose of protecting the life, physical integrity and health of persons other than the data subject or of the public in general, in the situations in which the data subject did not consent in writing and in an unequivocal way, can be done by the operator only after obtaining the authorization of the National Supervisory Authority. The authorization model is included in the Annex that is integral part of Decision No. 101/2008.⁵⁸

During the authorization issuing process the data controller shall notify the National Supervisory authority, or where applicable, shall complete/amend the previously registered notification.⁵⁹ It shall also fill a solicitation together with the exculpatory documents containing

⁵⁴ *Id.*, Article 22 Section (3).

⁵⁵ *Id.*, Article 23.

⁵⁶ National Authority for the Protection of Personal Data's Decision No. 11/2009, Article 1 Sections (1) and (2).

⁵⁷ The form, as well as all decisions of the National Supervisory Authority for Personal Data Processing are available in English at <http://www.dataprotection.ro/index.jsp?page=published&lang=en>

⁵⁸ Available in English at <http://www.dataprotection.ro/index.jsp?page=published&lang=en>

⁵⁹ The details of notification are listed in Section 6 of the present report.

at least the following information: the purpose of data processing, category or categories of the in question persons, personal data processed, estimated data for completing the processing operation, collecting source of the personal data, description of the data processing conditions and, where applicable of the reasons justifying the emergency.⁶⁰ For issuing the authorization, the National Supervisory Authority shall consult the Romanian College of Physicians.⁶¹

4. PECUNIARY ASPECTS

The collection and storage of human biological materials in biobanks is free, with the exception of the private stem cell banks that collect umbilical cord blood samples.⁶²

The collection of human organs, tissues and cells as a result of physical or moral pressure is forbidden.⁶³ Human organs, tissues and cells must not be donated for obtaining material and other types of benefits.⁶⁴ The donor, as well as the recipient shall sign a written declaration stating that the donation is a humanitarian act, it has an altruist character, and it is not done for obtaining material or any other benefits.⁶⁵

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

Human tissue and cells banks and any collection of human biological materials are based on the act of donation. According to the Romanian legislation the donation of human biological materials has to be preceded by the donor's consent. According to Article 144 (a) of Law No. 95/2006 a donor can be a living adult person, with full capacity to consent, who gives his or her informed, written consent prior to the collection of his or her biological materials. The consent shall be signed only after the person has been informed by the physician, social worker or other specialized person about the risks of the collection and its physical, psychic, familial and professional consequences.⁶⁶ The information has to include the purpose and nature of the collection, the tests that will be carried out, the information about data protection and confidentiality, furthermore the therapeutic scope. All these information have to be communicated in a language that is accessible to the donor.⁶⁷ The donor can change his or her mind with regard to donation until the collection of biological material takes place.⁶⁸

⁶⁰ Decision No. 101/2008, Article 2.

⁶¹ *Id.*, Article 4.

⁶² In the first private stem cell bank from Romania, The Cord Blood Center, Cluj the cost of the collection, transport, processing and testing of the samples is 3270 RON (~ 775 Euro) and in addition to this tax clients of this stem cell bank shall pay annually a tax for storage, that is 140 RON (~33 Euro). The webpage of the stem cell banks is http://www.cordcenter.ro/tarife_en.html

⁶³ Law No. 95/2006, Title VI, Chapter II, Article 144 (d).

⁶⁴ *Id.*, Article 144 (e).

⁶⁵ *Id.*, Article 144 (f).

⁶⁶ *Id.*, Article 144 (b).

⁶⁷ Decree No. 1242/2007, Article 2 Sections (2)-(3).

⁶⁸ Law No. 95/2006, Title VI, Chapter II, Article 144 (c).

According to Article 2.4 Section (a), Annex IV of Decree No. 1763/2007 the information registered in tissue and cell banks has to include “the consent/authorization, including the purpose/purposes (therapeutic and/or research) for which the tissues and cells shall be used for, as well as all the specific measures for destruction, if the tissues and cells are not used for the purpose for which the consent was given.”

The collection of human organs, tissues and cells from a living donor shall be done with the approval of the Commission for approval of donation from living donors.⁶⁹ This Commission shall evaluate the motivation of the donation and shall ensure the observance of patients’ rights.⁷⁰ The collection of blood, skin, sperm, umbilical cord blood, amniotic membranes from living donors can be done without the approval of the Commission, but with the observance of the bioethical norms set up by the Commission.⁷¹ If research is conducted on the collected human biological materials the persons from whom the material and data have been collected have to be informed about this and has to give their consent.

As a general rule persons without capacity to consent can not be donors.⁷² Article 145 Section (1) states that minors

are not allowed to become donors, unless otherwise specified by the Law. In these cases the collection of biological materials can be done only with the consent of the minor if he or she is between 14-18 years old, and the written consent of the parent or legal representative had been acquired. If the minor is less than 14 years old, the collection can be done with the consent of the parent or legal representative. If the minor refuses to consent the collection can not take place.

Extractions from deceased persons can be performed if the subject has expressed consent during his or her life, or if an adult member of his or her family consents, unless the person has opposed during his or her lifetime to being a donor after death.⁷³ In case of collection and processing of biological materials and data from deceased persons for research purposes Law No. 104/2003 applies. According to Article 19 the authorized units can obtain biological material from human cadavers for scientific and educational purposes if there is previous, written consent of the patient or his or her family; if a person during his life offers his or her body after death for such purposes or in case of cadavers that were not claimed in terms of 10 days after the death.

⁶⁹ The Commission has been set up with the Ministry of Health Decree No. 1076/2006 on the organization and functioning of the Commission for approval of donation from living donors, adopted on 5 September 2009, and entering into force on 7 September 2006. The members of the Commission have been appointed with Ministry of Health Decree No. 1597/2006, adopted on 11 December 2006, entering into force on 8 January 2007. The Commission shall include one medical doctor with specialization in bioethics, one psychologist or psychiatrist, one medical doctor, employee of the hospital in which the transplantation take place but who is not involved in the transplantation. Such Commission shall be set up in each hospital or health care institution (public or private) where transplantation involving living donors take place. The activity of these Commission are supervised by the Bioethics Commission of the Ministry of Public Health and the National Agency for Transplant.

⁷⁰ Law No. 95/2006.

⁷¹ *Id.*, Article 146 Section (6).

⁷² *Id.*, Article 144.

⁷³ *Id.*, Article 147-148.

Since biobanks contain not only human biological materials but personal identification data and health data, the provision of Law No. 677/2001 shall be also observed. According to Article 8 of the Law the processing of the personal identification number or of other personal data with a general identification function may be carried out only if the data subject has given express and unequivocal consent; or the processing is expressly stated by a legal provision. As a general rule processing personal data regarding the state of health is prohibited. This provision does not apply when the data subject has expressly given his or her consent for such data processing.⁷⁴

The rights of the data subjects in the context of personal data processing are set up in Chapter IV of Law No. 677/2001. As a general rule, when personal data are obtained directly from the data subject, the data controller is obliged to provide the data subject with the following information, except if the data subject already has this information:

- a) the identity of the data controller and, if required, of the data controller's representative;
- b) the purpose of the data processing;
- c) additional information, such as: the recipients, or the categories of recipients of the data; whether the requested information is compulsory, and the consequences of the refusal to provide it; the existence of the data subject's rights, stated by this law, notably the right of access, intervention and objection as well as the terms in which they may be exerted;

- d) any other information which may be expressly requested by the supervisory authority, considering the processing's specific situation.⁷⁵

When the data are not obtained directly from the data subject, it is the data controller's obligation, at the moment of collecting data or at least before the first disclosure takes place, if he has the intention to disclose the data to a third party, to provide the data subject with the above listed information, unless the data subject already possesses that information.⁷⁶ The provisions above do not apply when the processing of data is carried out for statistical, historical or scientific research purposes, or in any other situations if providing such information proves to be impossible or would involve a disproportionate effort towards the legitimate interest that might be damaged, neither do the above apply in case the recording or disclosure of the data is expressly stated by law.⁷⁷

Consent is also necessary in the case of research biobanks established at hospitals, and in case of biobanks not accredited for therapeutic purposes. In these cases biological materials and data are collected from the persons during their diagnosis and treatment and these materials can be used for research, if the persons consent. According to Article 18 of Law No. 46/2003 on Patients' Rights, the consent of the patient is obligatory for the collection, storage and processing of biological materials obtained from his or her body for diagnostic or therapeutic purposes. According to Article 19 the

⁷⁴ Law No. 677/2001, Article 7 Section (1). Other exceptions when the prohibition of the collection of personal health data does not apply are also enumerated in this Article.

⁷⁵ *Id.*, Article 12 Section (1).

⁷⁶ *Id.*, Section (2).

⁷⁷ *Id.*, Section (4).

patient's consent is obligatory in case of his or her participation in scientific research or educational activities. A person without capacity to consent shall participate in scientific research, only if her or his legal representative gives consent, and only if the person concerned benefits from the research.⁷⁸

The participation of human subjects in research shall be voluntary and shall take place only if the subject has been previously informed about the purpose and methods of the research, as well as the possible risks and benefits. In addition the subjects have to be informed that they can withdraw from the research at any moment without any negative consequence. The consent of the subjects has to be taken according to the legal provisions on this sense.⁷⁹ The refusal of a patient to take part in the research shall not influence the quality of physician-patient relationship.⁸⁰

Article 90 of Decision No. 3/2005 mentions those categories of persons that are more vulnerable, and who shall be given special attention during research. Such categories of persons include: persons without capacity to consent (minors, or persons who due to their health status do not have capacity to consent), persons who might give their consent under pressure (for example those in prison), persons who do not get direct personal benefit from the research (healthy volunteers) or persons for whom the research is combined with treatment (patients).

In case of minors the consent shall be obtained from the parents or legal repre-

sentatives, and the assent of the minor to participate in the research is also necessary. The involvement of minors in medical experiments shall be treated with the utmost attention and shall happen only when the risks are minimal.⁸¹ Persons who for whatever reasons do not have capacity to consent shall be included in research only when the research can not be carried out on persons with capacity to consent and when the risks are minimal.⁸² In such cases the consent shall be obtained from family members or legal representatives.⁸³

Article 109 stresses the importance of voluntary consent in case of clinical research aiming at the trial of certain diagnostic or therapeutic methods on human subjects.

6. ACCESS TO DATA AND SAMPLES

The Romanian Constitution as amended in 1991 guarantees the fundamental right to intimate, family and private life in its Article 26. The right to personal data protection is not expressly regulated by the Romanian Constitution, however it can be derived from other rights. The European regulations also dictate extensive data protection. The provisions of Directive 95/46/EC have been transposed into Romanian legislation by the adoption of Law No. 677/2001 on the protection of individuals with regard to the processing of personal data and the free movement of such data. The Romanian College of

⁷⁸ Law No. 46/2003, Article 19.

⁷⁹ Annex No. 2 of Decision No. 3/2005 of the Romanian College of Physicians on the adoption of the statute and the deontological code of the physician, Section: "Rules regarding human medical research", Article 98.

⁸⁰ *Id.*, Article 99.

⁸¹ *Id.*, Article 100.

⁸² *Id.*, Article 102.

⁸³ *Id.*, Article 101.

Physicians' Decision on the conditions of research on human subjects states that all necessary measures have to be taken to protect the privacy of the research subjects and to keep the confidentiality of any information about research subjects.⁸⁴ The patients' rights to privacy and to the confidentiality of their health data are protected by the Patients' Right Law.⁸⁵

Privacy and data protection issues are addressed by a number of legal instruments. According to Law No. 95/2006, Article 146 Section (7) data about both the donor and recipient, including genetic information, to which third parties might have access, shall be communicated in anonym form, so that neither the donor, nor the recipient can be identified. If the donor would like to keep his or her identity in secret the confidentiality of donation shall be respected, with the exception of those cases in which, in accordance with the law, the identity of the donor can not be kept secret.⁸⁶ The same rule applies when the donor is a deceased person.⁸⁷ The donated tissues and cells have to be identifiable by a unique code. The coded labeling of the donated tissues and cells shall allow the establishment of the link between the donor and the receiver, and vice versa.⁸⁸

Each donor, as well as the donated tissues and cells shall be provided either at the moment of collection or when the donated biological materials are registered in a biobank with a unique identifi-

cation code in order to assure the correct identification of the donor and the traceability of the donated biological materials. The coded data shall be introduced in a register with special regime that assures the security of personal data.⁸⁹ The tissue and cell banks shall have adequate systems of identification and labeling for the human tissues and cells that they receive and distribute.⁹⁰

Annex IV (1.4) of the Annex to Decree No. 1763/2007 details the necessary documentation of the donor. Each donor shall have a file containing the following items:

- a) identification of the donor (full name, date of birth, personal numeric code),
- b) age, sex, information about health status and behavior,
- c) the results of the medical check up,
- d) hemo-dilution form (if necessary),
- e) the consent form/authorization, in accordance with the legal requirements,
- f) clinical data, the results of laboratory and other tests,
- g) in case of autopsy the results have to be registered in a special document,
- h) in case of the donors of hematopoietic stem cells the eligibility of the donor for the chosen receiver also has to be documented.

The institution in which the collection of biological materials took place shall prepare a report of the collection that has to be sent to the tissue/cell bank.⁹¹ All the

⁸⁴ *Id.*, Article 103.

⁸⁵ Law No. 46/2003 on Patients' Rights, Chapter IV on the right of the patient to privacy and the confidentiality of information, Articles 21-25.

⁸⁶ Law No. 95/2006, Title VI, Article 146 Section (8).

⁸⁷ *Id.*, Article 148 Section (10).

⁸⁸ *Id.*, Article 160 Section (4).

⁸⁹ Annex to Decree No. 1763/2007, Article 2 Section (11).

⁹⁰ *Id.*, Article 11.

⁹¹ The items that shall be included in such report are detailed in 1.4.2, Annex IV of Annex to Decree No. 1763/2007.

registered information in the donor's file shall be clear and readable, protected from non-authorized modifications. For assuring a complete traceability the files shall be kept for at least 30 years after the clinical use or after the date of expiration, in an archive accredited by the National Transplant Agency.⁹² The packaging and labeling of the collected cells and tissues are also detailed in Annex IV.⁹³

It is important to note that the data that had to be registered in a biobank, among other items detailed under Article 2.4, shall contain the consent/authorization of the donor, including the purpose(s) of the donation (therapeutic and/or research), as well as all the specific instructions for the destruction of the tissues and cells if they are not used for the purpose for which the donor consented.⁹⁴ The necessary documentation for a biobank are also set up in the Annex V that lays down the criteria for the accreditation of human tissue and cell banks.⁹⁵ Annex X prescribes the minimum set of data that has to be registered by the tissue or cell bank, in accordance with Article 11, while Annex XI set up the information that has to be included in the European Coding System.⁹⁶

Law No. 677/2001 is the background for the Romanian regulation concerning medicine and biomedicine. This Law provides for both the rules of processing special categories of data, including data regarding the state of health, as well as the exceptions for processing special cat-

egories of data. As a general rule processing personal data regarding the state of health is prohibited.⁹⁷ Exceptions are allowed if:

- the data subject has expressly given his or her consent for such data processing;
- the processing is required in order to protect the data subject's life, physical integrity or health or that of another person which is legally or physically unable to express his or her consent;
- when the processing refers to data that had expressly been made public by the data subject;
- when the processing is required in order to ascertain, exercise or defend a right in a court of law;
- when the processing is required for preventive medical care, in order to establish a medical diagnosis, to provide medical care or treatment in the interest of the data subject, or to manage health services that are in the best interest of the data subject, on the condition that the processing of that data is performed by, or under the supervision of medical staff pledged to professional secrecy or by or under the supervision of another person subject to a similar obligation regarding the secrecy;
- where there is a specific legal provision, regarding the protection of an important public interest, on the condition that the processing is carried out in compliance with the rights of the data subject and other legal guarantees provided by Law No. 677/2001.⁹⁸

⁹² *Id.*, 1.4.3, 1.4.4.

⁹³ *Id.*, 1.5, 1.6.

⁹⁴ *Id.*, 2.4 (a).

⁹⁵ *Id.*, Annex V (E).

⁹⁶ Annex X and XI of the Annex to Decree No. 1763/2007.

⁹⁷ Law No. 677/2001, Article 7, Section (1)

⁹⁸ *Id.*, Section (2).

The same law provides expressly that the prohibition on processing health data doesn't apply if the processing is necessary for the protection of public health, or for the prevention of an imminent danger, the prevention of a criminal offence or the prevention of the result of such an act or for the alleviation of the damaging results of a criminal act.⁹⁹ The right to intimate, family and private life can be limited only for strictly defined purposes; the medical staff, health institutions and their staff may process personal health data without the authorization of the supervisory authority only when the data processing is required in order to protect the data subject's life, physical integrity or health. When the mentioned purposes refer to other people or to the general public and the data subject has not given his or her written and unequivocal consent, the preliminary authorization of the supervisory authority must first be obtained.¹⁰⁰ The details can be found in Decision No. 101/2008 of the Romanian National Supervisory Authority on establishing the procedure for the preliminary authorization.

The Romanian legislation makes sure that Romania participates in the establishment of a single European code, which will use a specific numerical code for identification of all human cells and tissues donated to the banks of cells and tissues, except for donation of reproductive cells between partners, where the aim is the precise identification of donors. According to Article 12 of Law No. 677/2001 at the moment of the establishment of a unique European code, a specific numeric code shall be used for the

identification of all tissues and cells donated to tissue and cell banks.

Each data controller shall be given a registration number. The registration number must be indicated on every document through which personal data are collected, stored or disclosed. The personal data processing register is available for public reference.¹⁰¹

The setting up of a large medical database or biobank can be a potential cause for danger from a data protection perspective. Therefore it is necessary to examine the foreseen processing of personal data for purposes not conceived at the initial data processing moment; the period of data retention; and the adequate security measures. Since research medical databases might be used after their establishment for different purposes than the original one, stringent data protection safeguards need to be met. For the protection of the privacy of data subjects, involved in human medical research, the obligation to apply data anonymization is a possible safeguard.¹⁰² According to Law No. 677/2001 anonymous data is data that, due to its specific origin or specific manner of processing, cannot be associated to an identified or identifiable person.¹⁰³

The National Supervisory Authority recommended the adoption of adequate security measures, at both technical and organizational levels. Accordingly data controllers must evaluate the potential risks for data processing, establish adequate security policies, inform and permanently specialize the employees, and establish the control on restricted access to avoid unauthorized access

⁹⁹ *Id.*, Article 9, Section (2).

¹⁰⁰ *Id.*, Article 9, Section (3).

¹⁰¹ *Id.*, Article 24.

¹⁰² Information presented in the lecture of Simona Zanfir, Legal Counselor at the National Supervisory Authority for Personal Data Processing, at the Tiss.Eu project workshop, 6-8 April, 2009, Budapest.

¹⁰³ Law No. 677/2001, Article 3 (i).

from administrative personnel or anyone else.¹⁰⁴

The processing of health data may be carried out only by, or under the supervision of medical staff who are under a pledge of professional confidentiality. Several exceptions to this rule include cases when the data subject has given, in writing his or her unequivocal consent, which has not been withdrawn, as well cases when the data processing is necessary for the prevention of an imminent danger, the prevention of a criminal offence or the prevention of the result of such an act or for the alleviation of the damaging results of such a criminal act. The medical staff, health institutions and their staff may process personal health data without the authorization of the supervisory authority only when the data processing is required in order to protect the data subject's life, physical integrity or health.¹⁰⁵ When the mentioned purposes refer to other people or to the general public and the data subject has not given his or her written and unequivocal consent, the preliminary authorization of the supervisory authority must first be demanded and obtained. The processing of personal data is forbidden beyond the limits of the authorization. Except for emergency reasons, the authorization may be given only after consulting the Romanian Medical College.¹⁰⁶

Personal health data may only be collected from the data subjects themselves. Exceptionally, these data can be collected from other sources only when it is required in order not to compromise the purpose of the processing, and when

the data subject cannot or doesn't wish to provide them.¹⁰⁷

At the end of the data processing operations, if the data subject has not given his or her express and unequivocal consent for another destination, or for further processing, the personal data shall be:

- a) destroyed;
- b) transferred to another data controller, provided that the former data controller guarantees the fact that the processing will have similar purposes to those of the former personal data processing;
- c) transformed into anonymous data and stored exclusively for statistical, historical or scientific research purposes.¹⁰⁸

Every data subject has the right to obtain from the data controller, upon request, and free of charge, once a year, the confirmation of the fact that the data concerning him or her are or are not being processed by the data controller. The data controller, in case he has processed any personal data concerning the petitioner, is obliged to communicate to the petitioner, along with the confirmation, at least the following:

- a) information regarding the purposes of the data processing, the categories of data concerned, and the recipients or the categories of recipients to whom the data are to be disclosed;
- b) communication in an intelligible form of the processed data and of any other available information regarding the source of origin of the respective data;

¹⁰⁴ *Id.*, Article 19, 20.

¹⁰⁵ *Id.*, Article 9, Sections (2)-(3).

¹⁰⁶ *Id.*, Section (4).

¹⁰⁷ *Id.*, Section (5).

¹⁰⁸ *Id.*, Article 6, Section (1).

- c) information on the technical principles and mechanisms involved in the data processing concerning that data subject;
- d) information concerning the existence of the right of intervention upon the data, and the right to object, as well as the conditions in which the data subject can exert these rights;
- e) information on the possibility of consulting the Register of personal data processing, stated under Article 24, before submitting a complaint to the supervisory authority, as well as to dispute the data controller's decisions in court, according to the provisions of this law;¹⁰⁹

The data subject might request the information stated under Section (1) from the data controller through a written, dated and signed petition. As a general rule the data controller is obliged to communicate the requested information, within 15 days of the receipt of the petition. In case of personal health data, the petition shall be filled in by the data subject him- or herself, or by medical staff who will mention the person on whose behalf the request has been made.

If the personal health data are processed for scientific research purposes, and if the risk of infringing the rights of the data subject does not exist and if the data are not to be used in order to take measures against a person, the data controller might communicate the requested

information within a period of time longer than 15 days, if otherwise the process or the outcome of the research would be affected. Even in such cases the communication of the information should not be delayed after the research has been completed. Such a delay is only allowed if the data subject has given his or her express and unequivocal consent for the data to be processed for the purpose of scientific research, as well as for the possible delay of the communication of the requested information.¹¹⁰

Every data subject has the right upon request to the data controller, and free of any charge to have his or her data rectified, updated, blocked deleted or anonymized, if the data processing did not comply with the provisions of the law.¹¹¹ The data subject has the right to object at any moment, based on justified and legitimate reasons linked to his or her particular situation, to a processing of data regarding him or her, unless there are contrary specific legal provisions. In case of justified opposition, the processing may no longer concern the respective data.¹¹²

In order to exercise the rights stated above the data subject shall fill a written, dated and signed petition. As a general rule the data controller has the obligation to communicate the measures taken within 15 days from the date of receipt of the petition.¹¹³

Chapter V of Law No. 677/2001 concerns the issue of confidentiality and security of processing. According to

¹⁰⁹ *Id.*, Article 13.

¹¹⁰ *Id.*, Article 13, Section (2-5).

¹¹¹ *Id.*, Article 14.

¹¹² *Id.*, Article 15. This is only a general rule, in case of research the subject is not obliged to justify or to tell the reason of withdrawal. Annex No. 2 of Decision No. 3/2005 of the Romanian College of Physicians on the adoption of the statute and the deontological code of the physician, Section: "Rules regarding human medical research", Article 98.

¹¹³ The exemptions to the provisions of Articles 12, 13, Article 14 Section (3) and Article 15 of Law No. 677/2001 are detailed in Article 16.

Article 19 any person who acts under the authority of the data controller or the data processor, including the data processor, who has access to personal data, shall process these personal data only in accordance with the data controller's specific instructions, except when the above-mentioned person's actions are based on a legal obligation. In line with Article 20 it is the data controller's obligation to apply the adequate technical and organizational measures in order to protect the data against accidental or unlawful destruction, loss, alteration, disclosure or unauthorized access, notably if the respective processing involves the data's transmission within a network. Protection shall also extend to any other form of illegal processing. These measures shall ensure – depending on the state of the art techniques employed and the costs – adequate safeguards against processing risks; and they shall as also take the nature of the data to be protected into account. The minimum security requirements shall be issued by the supervisory authority and shall be periodically updated, according to the technological progress and the accumulated experience. When appointing a data processor, the data controller has the obligation to assign a person who presents sufficient guarantees regarding technical security and the organizational measures concerning the data to be processed, as well as the obligation to ensure that the assigned person complies with these measures. The supervisory authority shall decide, on a case by case basis, whether the data controller should adopt additional security measures.

7. STORAGE AND DISTRIBUTION

The information related to the donated tissues and cells shall be kept for at least 30 years.¹¹⁴ According to the Methodological Norms for the application of Title VI of Law No. 95/2006 the health institutes accredited for human tissue and/or cell banking activities and the users of such banks shall keep a register of their activities, including the types and quantity of distributed human tissues and cells collected, tested, conserved, stored or distributed, as well as the origin and destination of these materials on hard copies, magnetic copies and microfilm for a period of 30 years.¹¹⁵

Annex VI of the Annex to Decree No. 1763/2007 set up the conditions of storage, distribution and withdrawal of tissues and cells from a biobank. The maximum period for which tissues and cell can be stored has to be specified for each tissue and cell deposited in a biobank. The collection of tissues and cells in a biobank has to be kept under a strict inventory, and tissues and cells can be released and distributed only if all the legal conditions are met, and only in accordance with the standard operation procedures. The biobanks shall set up a specific procedure for the withdrawal of tissues and cells from the biobank. In each case of withdrawal the National Transplant Agency shall be notified. The biobank shall set up a protocol for registering each request of tissue or cell and shall prepare the rules of tissue and cell allocation for patients and health care institutions.¹¹⁶

Article 6 of Decree No. 1242/2007 refers to the import and export of human

¹¹⁴ Law No. 95/2006, Title VI, Chapter VI, Article 160 Section (4).

¹¹⁵ Methodological Norms for the application of Title VI, of Law No. 95/2006, Article 10, and Article 11 (2) of Annex to Decree No. 1763/2007.

¹¹⁶ Annex VI of Annex to Decree No. 1763/2007, points B and C.

tissues and cells. Both import and export shall be authorized by the National Transplant Agency. All professional relationships between biobanks and other public or private entities (other biobanks, hospitals or firms) shall take place based on written agreements between the parties. The National Transplant Agency shall be provided with copies of these agreements.

As background legislation the data protection rules may be invoked again. According to Article 4, Section (e) of Law No. 677/2001 personal data which are intended to be processed must be stored in a manner that allows the identification of the data subject only for the time period required to fulfill the purposes for which data are collected and later processed. The storage of data for a longer period of time, for statistical, historical or scientific research purposes, shall be carried out in accordance with the guarantees regarding personal data processing laid down in the relevant legal framework, and only for the period of time required to achieve these purposes.

Chapter VII of Law No. 677/2001 concerns the transfer abroad of personal data. Article 29 of the law laid down the conditions for the transfer abroad of such data. According to Section (1) of Article 29 the transfer abroad of data that are subject to processing or are destined to be processed after being transferred shall only take place if the Romanian law is not infringed and the state of destination ensures an adequate level of data protection. As a general rule, the data transferred to another state shall be subject to prior notification to the supervisory authority.

The data transfer is always allowed when the data subject has explicitly given his or her consent for the transfer (if the data transfer is linked to special category of data, the consent must be written) or when it is required in order to protect the data subject's life, physical integrity or health.¹¹⁷ If the processed data is intended to be transferred abroad, the notification shall consist of the data categories subject to the transfer and the country of destination for each data category.¹¹⁸

The National Supervisory Authority for Personal Data Processing has issued Decision No. 10/2009 regarding the establishment of an authorization model for the transfer of personal data abroad based on the provisions of Article 29 Section (4) of Law No. 677/2001 for the protection of persons regarding the processing of personal data and the free movement of such data. The Decision approves the model of authorization for the transfer abroad of personal data based on art. 29 Section (4) of Law 677/2001, as modified and amended, that is included in the Annex to the Decision.

The Romanian data controllers providing health services notified the National Supervisory Authority for Personal Data Processing in several cases about transferring personal data abroad and requested authorization for the following purposes: the execution of clinical studies and the improvement of the medical services' quality, and experimental clinical studies of testing new medicines on human subjects. The aforementioned purposes involved special data transfers, such as biometric data, genetic data, data related to the health condition, series and number of the identity

¹¹⁷ Law No.677/2001 Article 30.

¹¹⁸ *Id.*, Article 22 Section (6).

document, personal identification number, etc. Such data have been transferred to data management companies, companies for the statistical processing of data as well as collaborating agencies/investors (medical staff).¹¹⁹

8. SUPERVISION, COMPENSATION, PENALTIES

The supervising authorities for biobanks related activities are the National Transplant Agency, the National Supervisory Authority for Personal Data Processing, Ministry of Public Health, Ministry of Education and Research, Romanian College of Physicians, National Research Ethics Committee, and National Authority for Scientific Research.

The National Transplant Agency has the right to suspend or recall the accreditation of a biobank if it turns out during inspection that the relevant and applicable legal provisions are not observed. Inspections shall be periodic, and the period between two inspections shall be no longer than 2 years.¹²⁰

The National Authority for the Supervision of Personal Data Processing set up under Law No. 102/2005 exercises the competence established mainly by Law No. 677/2001, independent from any public authority or private entity. The competences of the National Authority for the Supervision of Personal Data Processing include the investigation of personal data processing conducted

under Law No. 677/2001 and the sanctioning, if it is established – either as a result of self-notification or due to an investigation started on the basis of a complaint filed by a person concerned – that the legal dispositions were infringed by the personal data processors.¹²¹

According to Article 27 of Law No. 677/2001 the supervisory authority may investigate *ex officio* or as a result of a complaint, any infringement of the data subject's rights, of the controller's obligations and, as the case may be, the obligations of the processors, in order to protect the fundamental rights and freedoms of the data subjects. The supervisory authority may not exercise its investigative powers in case a complaint of the same alleged breach and among the same parties was previously submitted to a court of law. In the exercise of its investigative powers, the supervisory authority may request any information linked to the processing of data from the data controller and may verify any document or record regarding the processing of personal data.

Without prejudice to the possibility of addressing the supervisory authority, the data subject has the right to turn to a court of law in defense of any rights, guaranteed by the Law No. 677/2001. Any person that has suffered a violation of his or her rights as a consequence of unlawful processing of personal data may turn to a competent court of law in order to obtain compensation for the violation suffered.¹²² In order to defend the rights set out by the Law No.

¹¹⁹ Simona Zamfir: "The processing of personal data regarding the state of health and human medical research in Romania", unpublished paper.

¹²⁰ Law No. 95/2006, Article 160 Section (3).

¹²¹ <http://www.dataprotection.ro/index.jsp?page=home&lang=en>

¹²² Law No. 677/2001, Article 18.

677/2001, the persons whose personal data are processed under the terms of this law may file a complaint with the supervisory authority. The complaint may be submitted directly or through a representative. The data subject may empower an association or a foundation to represent his or her interests. The complaint submitted to the supervisory authority is invalid if a claim, concerning the same matter and parties, was previously submitted to a court of law.¹²³

The collection of organs, tissues and/or cells of human origin without the consent obtained under the conditions laid down in Title VI of Law 95/2006 constitutes a crime and shall be punished by 5 to 7 years imprisonment.¹²⁴ According to Article 157 Section (1) of the same Law donation of human organs, tissues and/or cells with the purpose of obtaining material or other type of benefit is a crime and shall be punished by 3 to 5 years detention. Forcing or influencing somebody with bad intentions to donate human organs, tissues and/or cells is a crime and shall be punished with 3 to 10 years detention. Advertising for obtaining human organs, tissues and cells for the benefit of a person, as well as advertising the donation of human organs, tissues and/or cells for obtaining material or other type of benefits for the donor or for the organizer of the donation, for the family or for third parties, is a crime and shall be punished by 2 to 7 years of detention.¹²⁵

Importing or exporting human organs, tissues and/or cells, without the special authorization of the National Transplant Agency is a crime and shall be punished by 3 to 10 years of detention.¹²⁶ In line with Article 27 of Law No. 104/2003 the collection of tissues and cells from cadavers that do not follow the provisions of the Law is crime and can be penalized by 1 to 3 years of detention.¹²⁷

According to Article 193 of the Romanian Penal Code, purposefully altering, by any means, the human genotype is a criminal act. The production of biological weapons or other weapons for mass killing with the help of genetic engineering is a crime.¹²⁸ The creation of a human embryo for other purposes than procreation, as well as cloning a human being is a crime.¹²⁹ The medical doctor or any other health care professional commits a crime by violating professional secrecy, or by disclosing any health related information without the patient's consent, if this causes material or moral harm for the patient. The medical professionals can be punished by 3 months to 2 years detention, or by fines.¹³⁰

In line with Article 31 of Law No. 677/2001 failure to submit the compulsory notification under the terms set out by law, or to submit incomplete notification or one that contains false information – if the respective maladministration falls short of a criminal offense –, is considered as a minor offense punishable by a fine of 5 million to 100 million ROL

¹²³ *Id.*, Article 25.

¹²⁴ Law No. 95/2006, Title VI, Chapter V. Article 155.

¹²⁵ *Id.*, Article 157 (2-3).

¹²⁶ *Id.*, Article 159.

¹²⁷ Law No. 104/2003, Article 27.

¹²⁸ Romanian Penal Code, Chapter IV, Article 194.

¹²⁹ *Id.*, Article 195 (1-2).

¹³⁰ *Id.*, Article 196.

(Romanian currency – lei).¹³¹ The processing of personal data by a controller or by a person empowered by the data controller, breaching the provisions of Articles 4-19, or disregarding the rights set out in Articles 12-15 or in Article 17 is considered a minor offense if the respective maladministration falls short of a criminal offense and is fined by 10 million to 250 million ROL.¹³² Failure to fulfill the obligations regarding the enforcement of the security measures provided by Articles 19 and 20, as well as breach of confidentiality are minor offenses, if the respective maladministration falls short of a criminal offense and the person committing these offenses is liable to a fine of 15 million to 500 million ROL.¹³³ The refusal to

supply the requested information or documents to the supervisory authority in the exercise of its investigative powers is considered a minor offense, if the respective maladministration falls short of a criminal offense and the entity in question can be fined by 10 million to 150 million ROL.¹³⁴

9. PUBLIC DEBATE

According to Law No. 52/2003 on decisional transparency, before adopting a law it has to be accessible and open for public consultation. The laws adopted after the entering into force of Law No. 52/2003 still have to fulfill this requirement.

¹³¹ Chapter VIII of Law No. 677/2001, Article 31.

¹³² *Id.*, Article 32.

¹³³ *Id.*, Article 33.

¹³⁴ *Id.*, Article 35.

FORENSIC BIOBANKS

1. RELEVANT LAWS

Law No. 76 from 8 April 2008 on the Organizing and Functioning of the National Judicial Genetic Data System (N.J.G.D.S.) is the main law that regulates forensic biobanks in Romania.¹³⁵ This law prescribes the conditions in which biological evidence can be collected from certain natural persons or from biological traces left at the crime scenes with the purpose of determining the genetic profile. The law also lays down the conditions under which data comprised by the N.J.G.D.S. can be processed. Other relevant legal norms will be the Methodological Norms for the application of the above mentioned Law No. 76 and for the creation of a national legal framework for the implementation of Council Decision 2008/615/JHA of 23 June 2008 on the stepping up of cross-border cooperation, particularly in combating terrorism and cross-border crime, as it regards the automatic transfer of genetic pro-

files.¹³⁶ The final draft of the norm is currently reviewed by various experts, and the technical details are clarified in consultation with representatives of the National Supervisory Authority for Personal Data Processing, representatives of the Ministry of Health, and other authorities.¹³⁷

Since the collection, storage and processing of biological materials implies collection, storage and processing of personal data too, another significant law that applies to the National Judicial Genetic Data System is Law No. 677/2001 for the Protection of Individuals Concerning the Processing of Personal Data and Free Movement of Such Data. According to Article 1 Section (5), Law No. 677/2001 also applies – within the limitations set out by the law – to the processing and transfer of personal data, carried out within the activities of preventing, investigating and repressing criminal offences and maintaining public order, as well as other activities in the field of criminal law.

¹³⁵ In original language: Legea Nr. 76 privind organizarea și funcționarea Sistemului Național de Date Genetice Judiciare, available at http://www.cdep.ro/proiecte/2008/000/10/8/leg_pl018_08.pdf, adopted on 8 April 2008, entering into force on 14 November 2008.

¹³⁶ In original language: Guvernul României: Hotărâre pentru aprobarea Normelor metodologice de aplicare a Legii nr. 76/2008 privind organizarea și funcționarea Sistemului Național de Date Genetice Judiciare și pentru crearea cadrului legal intern necesar aplicării Deciziei 2008/615/JAI a Consiliului din 23 iunie 2008 privind intensificarea cooperării transfrontaliere, în ceea ce privește transferul automatizat al profilurilor genetice. The draft version of the norms in Romanian language can be accessed at <http://www.mai.gov.ro/Documente/Transparenta%20decizionala/HG%20GENETICA.pdf>

¹³⁷ Dr. Mariana Aurelia Bistriceanu, Legal Counselor at the Ministry of Administration and Internal Affairs explained that it requires a long process of negotiation to clarify all the technical details that occur during the application of Law 76/2008. The most sensitive issues are connected to consent and international exchange of data.

In addition to these norms the Constitutional Court Decision No. 485/2009 on the constitutionality of Article 5 Section (3) of Law No. 76/2008 on the Organizing and Functioning of the National Judicial Genetic Data System is also of relevance in this field.¹³⁸

2. MANAGEMENT AND SUPERVISION

The National Judicial Genetic Data System is managed by the Institute for Criminology of the Romanian Police, and it is supervised by the Ministry of Administration and Internal Affairs.¹³⁹ The necessary funds for the establishment and functioning of the N.J.G.D.S. shall be secured from the sums especially allocated for this purposes from the state budget, from the budget of the Ministry of Administration and Internal Affairs.¹⁴⁰

According to Article 19 of the Law No. 76/2008 30 days after the entry into force of the law, the Ministry of Administration and Internal Affairs and the Ministry of Justice shall draw up the Methodological Norms for its application referring to the harvesting of biological evidence, to the registering of personal information data, to performing of genetic analyses and to conveying of data. These methodological

norms are currently reviewed by the experts. The final version will be adopted through a Governmental Decision.

The National Authority for the Supervision of Personal Data Processing set up by the Law No. 102/2005, exercises the competence established mainly by Law No. 677/2001 on Data Protection, include the investigation of personal data processing conducted under Law No. 677/2001 and the sanctioning, if it is established – either as a result of self-notification or due to an investigation started on the basis of a complaint filed by a person concerned – that the legal dispositions were infringed by the personal data processors.¹⁴¹ These competences are applicable in relation to the N.J.G.D.S. too, within the limitations laid down by law.

3. SAMPLES AND SAMPLE TAKING, CONSENT

The collection of biologic evidence (biological traces that have in their composition cells, tissues or human secretions) is done by non-invasive methods, either by harvesting of epithelial cells by brushing the buccal mucosal surface, or if this is not possible, by harvesting of epithelial cells from the facial region.¹⁴² Further technical details in

¹³⁸ In original language: Curtea Constituțională, Decisia Nr. 485 din 2 aprilie 2009 referitoare la excepția de neconstituționalitate a dispozițiilor articolului 5 aliniat (3) din Legea nr. 76/2008 privind organizarea și funcționarea Sistemului Național de Date Genetice Judiciare, adopted on 2 April 2009, entering into force on 4 May 2009.

¹³⁹ Ministry of Internal Affairs and of Administrative Reform, when the Law No.76/2008 on N.J.G.D.S. was adopted, currently Ministry of Administration and Internal Affairs.

¹⁴⁰ Law No. 76/2008, Article 18.

¹⁴¹ <http://www.dataprotection.ro/index.jsp?page=home&lang=en>

¹⁴² Law No. 76/2008, Article 5, Section (1). This provision implies that buccal swab taking is not invasive. Although this is disputed in the academic literature, we are not going to take a position in the present analysis.

relation to the collection of biological materials are going to be included in the Methodological Norms for the application of Law No. 76/2008.

In the case of suspects (persons about whom data and information exists suggesting that they might be perpetrators, instigators or accomplices in offenses listed in the Annex to the Law No. 76/2008 – see section 4 of the report on this) biological evidence can be collected upon their consent, at the written request of the criminal investigation authorities or of the court.¹⁴³ If the persons from whom biological evidence is to be collected, or, in the case of minors aged between 14 and 18 years, the minor's parents or legal representative refuse to submit such evidence, the organ in charge with the collection shall inform the court, which will decide whether biological evidence may or may not be collected in the absence of the concerned persons' consent. The Romanian Constitutional Court has issued a decision concerning the sample taking and storage whenever minors are involved (see Section 7 of this Report). Collection of biological evidence from minors under 14 years with the scope of establishing a genetic profile can be done only with the parents' or the legal representative's consent and in their presence.¹⁴⁴

The courts and criminal investigation authorities that order the collection of evidence are obliged to inform the suspects and persons convicted - for the commission of offenses listed in the Annex of the

Law No.76/2008 that the collected biological evidence will be used for obtaining and storing their genetic profiles in the N.J.G.D.S.¹⁴⁵

In penal cases, collection, preservation and transportation of biological evidence from suspects, with the purpose of registering their genetic profiles in the N.J.G.D.S., are effected by the specially trained personnel of the Romanian Police, at the request of the criminal investigation authorities and/or of the courts. The specially trained personnel of the Romanian Police may also collect, preserve and transport biological evidence from persons who have had contacts with the crime scene, as well as from the victims upon their consent.¹⁴⁶ In the case of suspects and persons who have had contacts with the crime scene – even if these contacts are accidental –, as well as from the victims upon their consent biological evidence can also be collected by qualified medico-sanitary personnel.¹⁴⁷

In the case of persons convicted to imprisonment by means of a final judgment for the commission of offenses listed in the Annex of Law No. 76/2008, collection of biological evidence is ordered by the court through the judgment sentencing the person charged.¹⁴⁸ In this case the collection of biological evidence with the purpose of registering their genetic profiles in the N.J.G.D.S. is effected upon their release from detention, by the penitentiary's medical personnel with the sup-

¹⁴³ *Id.*, Section (2).

¹⁴⁴ *Id.*, Article 5, Section (4).

¹⁴⁵ *Id.*, Article 5, Section (5).

¹⁴⁶ *Id.*, Article 6, Section (1).

¹⁴⁷ *Id.*, Article 6, Section (2).

¹⁴⁸ *Id.*, Article 7, Section (1).

port of the staff and in the presence of a police officer, without a previous court decision.¹⁴⁹

At the crime scenes, biological evidences are collected by the specialized police personnel. Collection of biological evidence from unknown corpses, harvesting of cells at autopsies, as well as collection of biological evidence through invasive methods are performed by medico-legal institutions.¹⁵⁰

4. PURPOSE AND SCOPE OF COLLECTION

According to the Law No. 76/2008 the purpose of the National Judicial Genetic Data System is the prevention and against a category of offenses, which seriously breach fundamental rights and freedoms of the person, especially the right to life and to physical and psychic integrity, as well as the identification of unknown corpses, of missing persons or of corpses after mass disasters, murder victims or victims of terrorist acts.¹⁵¹

Within the N.J.G.D.S. genetic profiles and personal data are verified and compared for:

- a) excluding persons from the circle of suspects and identifying the authors of the offenses listed in the Annex to the Law No.76/2008;
- b) establishing the identity of persons – victims of natural disasters, mass accidents and acts of terrorism;
- c) effecting information exchange with

other states and combating cross-border criminality;

- d) identifying those involved in the commission of the offenses listed in the Annex.¹⁵²

According to Article 3 of Law No. 76/2008 the offenses in the case of which biological evidence may be collected with the purpose of introducing the genetic profiles in the N.J.G.D.S. are the following: homicide; first degree homicide; aggravated homicide; infanticide; manslaughter; triggering or facilitating suicide; battery; aggravated battery; hitting or injury causing death; battery by negligence; illegal deprivation of liberty; slavery; rape; sexual intercourse with a minor; sexual perversion; sexual corruption; incest, robbery, torture; non-compliance with the legal regime of nuclear material or other radioactive material; non-compliance with the legal regime of explosives; ill treatment applied to minors; propaganda in favor of war; genocide; inhuman treatment; destruction and appropriation of property; destruction, robbery or appropriation of cultural values; terrorist acts; offenses provided for by Articles 2, 3, 10 and 12 of Law No. 143/2000 on combating drug trafficking and illicit drug administration, as amended; and the offense provided for by Article 22 Section (3) of Governmental Emergency Ordinance No. 121/2006 on the legal regime of drug precursors, approved with amendments by Law No. 186/2007.¹⁵³

¹⁴⁹ *Id.*, Art 7, Section (2).

¹⁵⁰ *Id.*, Article 8.

¹⁵¹ *Id.*, Article 1 Section (1).

¹⁵² *Id.*, Article 1 Section (2).

¹⁵³ Annex of Law No. 76/2008.

According to Article 4 Section (1) of Law No. 76/2008, the N.J.G.D.S. handles genetic profiles, personal data and information about criminal cases, corresponding to the following categories:

- a) suspects – persons about whom data and information exists suggesting that they might be perpetrators, instigators or accomplices in offenses listed above;
- b) persons convicted to imprisonment by means of a final judgment for the commission of offenses listed above;
- c) biological traces collected at crime scene investigation;
- d) unknown corpses, missing persons or persons deceased in natural catastrophes, mass accidents, homicides or terrorist acts.

Persons not belonging to the above categories can also be included in the N.J.G.D.S. through a Governmental Decision taken upon the proposal of the Ministry of Justice and the Ministry of Administration and Internal Affairs, in accordance with the necessities and the allocated resources. With the purpose of excluding those persons who had contacts with the crime scene, biological evidence can be collected from them, as well as from the victims, upon their consent. The genetic profile of the above mentioned categories of persons will not be stored in the database, they will be verified by comparison within the N.J.G.D.S. only with regard to the specific offense and in line with the scope for which the evidence was collected.¹⁵⁴

5. ACCESS TO DATA AND SAMPLES

The General Inspectorate of the Romanian Police (G.I.R.P.), subordinated to the Ministry of Administration and Internal Affairs, is the authority in charge with the processing of data stored in the N.J.G.D.S., through the Institute of Forensics, which acts as administrator of the N.J.G.D.S.¹⁵⁵ Data stocked in the N.J.G.D.S. is accessible to the criminal investigation authorities and to the courts in penal cases, to the Romanian Intelligence Service when fulfilling its legal duties in the field of preventing and combating terrorism, as well as to judicial authorities of third states, on reciprocal basis or on the basis of international agreements to which Romania is party.¹⁵⁶ International requests of interrogation, search and verification of data in the N.J.G.D.S. can be made through the Romanian Center for International Police Co-operation or other officially established channels.¹⁵⁷

Biological evidence collected according to the provisions of the present law, and the data stored in the N.J.G.D.S. can be used only for the purposes that are specified in Law No. 76/2008.¹⁵⁸

Processing of data stocked in the N.J.G.D.S. can take place on the basis of an official request of the crime investigation authorities or of the court. When processing data registered in the N.J.G.D.S., the provisions of Law No. 677/2001, with all its subsequent amendments shall be observed. The actual data processing methods, including the necessary forms, will be

¹⁵⁴ Law No. 76/2008, Article 4, Section (2-4).

¹⁵⁵ *Id.*, Article 9 Section (1).

¹⁵⁶ *Id.*, Article 9 Section (3).

¹⁵⁷ *Id.*, Article 9 Section (4).

¹⁵⁸ *Id.*, Article 10.

established by the Methodological Norms for the application of the present law.¹⁵⁹

The Laboratory of Judicial Genetic Analysis within the G.I.R.P. is authorized to have access and to analyze biological evidence collected from the categories enumerated in Article 4 Section (1). Judicial genetic analysis can be conducted also by other laboratories, accredited according to the international ISO 17025 standards.¹⁶⁰ The genetic profiles registered in the N.J.G.D.S. shall not comprise information about health or other individual characteristics that may breach the right to intimate, family and private life.¹⁶¹

According to Article 10 of Law No. 677/2001 processing personal data regarding criminal offenses, or regarding previous criminal convictions, security measures or administrative or minor offense sanctions applied to the data subject, may be carried out only under the control of public authorities, within the limits of their powers determined by law, especially specialized pieces of legislation. The supervisory authority may establish other cases in which the data processing described under Article 10 Section (1) may be carried out, provided that adequate guarantees are put in place to observe the rights of the data subject. A complete record of criminal convictions may be kept only under the control of a public authority.¹⁶²

6. STORAGE AND DATA TRANSFER

The genetic profiles obtained from suspects and registered within the N.J.G.D.S. are stored until the crime investigation authorities or a court order to be deleted from the database. Stocking of genetic profiles, of personal information and of information on the case is done through electronic means by saving them in folders on designated servers.¹⁶³ If penal prosecution did not start, has been stopped, or the court proceedings discontinued, or the data subject has been acquitted, data stored in the N.J.G.D.S. can be deleted on the basis of the prosecutor's ordinance or resolution, or, accordingly, on the basis of the court decision, if it comprises any such reference; these cases will be notified to the N.J.G.D.S.'s administrator.¹⁶⁴

Genetic profiles registered in the N.J.G.D.S. and obtained from persons convicted to imprisonment in a final judgment for having committed offenses listed in the Annex of Law No. 76/2008, are stored until the person concerned reaches the age of 60, or if the convict deceased prior of the age of 60, for an additional 5 years after his or her death.¹⁶⁵

Biological evidence left after genetic analysis from suspects and from persons convicted to imprisonment by means of a final judgment for the commission of offenses listed in the Annex of Law No. 76/2008 shall be preserved at specially designed places and shall be destroyed

¹⁵⁹ *Id.*, Article 9, Section (5-7).

¹⁶⁰ *Id.*, Article 11, Section (1).

¹⁶¹ *Id.*, Article 12.

¹⁶² Law No. 677/2001, Article 10, Section (3).

¹⁶³ Law No. 76/2008 Article 13 Section (1).

¹⁶⁴ *Id.*, Article 13, Section (2).

¹⁶⁵ *Id.*, Article 14.

only at the time when genetic profiles are deleted from the database.¹⁶⁶

Genetic profiles obtained from the unknown corpses, missing persons or persons deceased in natural catastrophes, mass accidents, homicides or terrorist acts and from the traces collected from the crime scenes shall be preserved until positive identification, or for 25 years from the date of their registration; no prior notification being necessary for erasing them.¹⁶⁷ Genetic profiles belonging to these categories of persons can be compared, for the purpose of identification, only to the genetic profiles of first- and second-degree relatives. The relatives' genetic profiles, established with the purpose of identification shall not be stored in the database.¹⁶⁸

Chapter VII of Law No. 677/2001 concerns the transfer abroad of personal data. Article 29 sets up the conditions of transferring personal data abroad. According to Section (1) of this Article the transfer of data that are subject to processing or are destined to be processed after being transferred may take place only if the Romanian law is not infringed and the state of destination ensures an adequate level of protection. According to Section (3) data transferred to another state shall always be subject to prior notification to the supervisory authority. The provisions of Section (3) do not apply in case the data transfer is based on a special law or on an international agreement ratified by Romania, notably if the transfer is done for the purpose of prevention, investigation or repression of a criminal offense.

7. CONSTITUTIONAL COURT DECISION

The Constitutional Court Decision No. 485/2009 on the constitutionality of Article 5 Section (3) of the Law No. 76/2008 on the Organizing and Functioning of the National Judicial Genetic Data System concerns the issue of privacy. According to the challenged provision if the persons from whom biological evidence is to be collected, or in the case of minors aged between 14 and 18 years, the parents or the legal representative refuse to submit such evidence, the organ in charge with the sample collection shall inform the court, which will decide whether biological evidence may or may not be collected in the absence of the concerned persons' consent.

A lower court submitted a constitutional complaint to the Constitutional Court in relation to the collection of biological samples from a minor suspect.¹⁶⁹ The applicant claimed that the Public Ministry's request for sample taking was unconstitutional. The applicant based his claim on the Romanian Constitution's provisions, notably on Article 26 on the protection of private and family life and on Article 20 of the International Treaties on Human Rights, especially on the provision that refers to Article 8 of the Convention for the Protection of Human Rights and Fundamental Freedoms, concerning the rights to privacy and family life.

According to the applicant the request of the public authority for the collection of biological samples from the suspect

¹⁶⁶ *Id.*, Article 17.

¹⁶⁷ *Id.*, Article 16.

¹⁶⁸ *Id.*, Article 4, Section (6).

¹⁶⁹ Case No. 108/118/2008.

intruded into the private life of the person concerned, and such intrusions are impermissible in a democratic society. Based on Article 30 Section (1) of Law No. 47/1992 the case has been communicated to the Presidents of the two Chambers of the Romanian Parliament, to the Romanian Government and to the Peoples' Lawyer, giving them the opportunity to formulate their opinions on the potential unconstitutionality.

The Peoples' Lawyer argued that according to Article 1 Section (1) of Law no. 76/2008 the purpose of the Law is to establish the National Judicial Genetic Data System, for preventing and fighting a category of offenses, which seriously violate fundamental rights and freedoms of the person, especially the right to life and to physical and psychical integrity. Another purpose is the identification of unknown corpses, of missing persons or of corpses after mass disasters, murder victims or victims of terrorist acts. All these purposes are, however in line with the Article 8 of the Convention for the Protection of Human Rights and Fundamental Freedoms. Accordingly, the provisions of Article 5 Section (3) are not unconstitutional.

The Presidents of the two Chambers of the Parliament and the Government have not formulated their views about this case.

The Constitutional Court has examined all these opinions and the laws that have been referred to. The Court stated that the rights mentioned in Article 8 of the Convention for the Protection of Human Rights and Fundamental Freedoms are not absolute rights, but they can be sub-

ject to certain limitations or restrictions by state authorities. One of the rights mentioned in Article 8 is the right to privacy, but this right can be subject to limitations upon the condition that these limitations are prescribed by law, are legitimate, that they appear as necessary in a democratic society, are connected to a right protected by the Convention, and are proportionate to the aim to be achieved. Taken all these into account the Court considered that it is obvious that every citizen is obliged to subject him- or herself to the principle of finding the truth. As a result, the genetic analysis of the biological materials collected at the crime scene, as well as the analysis of biological materials collected from suspects, is a legitimate measure in a democratic society.

According to Article 5 Section (3) the judge, as a representative of the authorities has the right to order the collection of biological materials, even if the person from whom these will be collected did not consent. Taken Article 1 Section (1) of Law No. 76/2008 into account, according to the Court it is obvious that the scope of the request is perfectly in line with the requirements of Article 8 Section (2) of the Convention for the Protection of Human Rights and Fundamental Freedoms and with Article 53 of the Romanian Constitution, so the interference of the authority in the private and family life is justified.

For the above mentioned reasons the Constitutional Court decided to reject the application concerning Article 5 Section (3) of Law No. 76/2008. The decision has been rendered on 2 April 2009.





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