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C E L A B

JUDIT SÁNDOR
PETRA BÁRD

THE LEGAL REGULATION OF BIOBANKS

National Report: Cyprus

GeneBanC

CENTER FOR ETHICS AND LAW IN BIOMEDICINE
CEU

Editors: Judit Sándor and Petra Bárd

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Address: 1051 Budapest Nádor u. 9. Hungary
Telephone: +36-1-472-3403
Fax: +36-1-354-1599
E-mail: celab@ceu.hu
Website: http://www.ceu.hu/celab
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THE REGULATORY FRAMEWORK OF THE ESTABLISHMENT, MANAGEMENT AND FUNCTIONING OF BIOBANKS IN CYPRUS

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 genetic 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 to 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.

We would like to express our gratitude to Dr. Judit Schvéger for her editorial support.

The present booklet summarizes the regulatory framework of biobanks in Cyprus and focuses on the collection and analysis of legislation and regulation regarding the establishment, management and functioning of classical and forensic biobanks. The former will be discussed 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 international standards, or pieces of European Union law, but it should be borne in mind that they are binding on Cyprus being a European Union Member State.

Budapest, 31 July 2009

I. CLASSICAL AND POPULATION BIOBANKS

1. DEFINITION OF BIOBANKS

Cyprus is known to have an increased frequency of inherited disorders, which place a heavy burden on the Government to provide sufficient legislative and social framework for the services and researches aimed towards early detection and prevention of such diseases.[1] The provision of high quality medical services and in general improvement in the quality of life of the community is one of the main goals of the Cypriot government in relation to its Health Policy.[2] Although Cyprus has not adopted special legislation for the regulation of biobanks, the relevant legal instruments that are applicable in data protection concerning tissue banks and transplantation are in compliance with the European standards. In the absence of a special regulative framework on the establishment and management of biobanks, a fragmented legislative structure of generally applied constitutional provisions, laws, regulations, legal notices, codes of practice, guidelines and so forth are potentially applied.

2. RELEVANT LAWS

Cyprus has transposed all the relevant pieces of the *acquis communautaire* that are dealing with transplantation standards for the quality and safety of tissues and cells throughout the transplantation process. The respective legislations are Directive 2004/23/EC, Directive 2006/17/EC and Directive 2006/86/EC that are adopted by the Comission of the European Communities. The Commission Directive 2006/17/EC implementing Directive 2004/23/EC of the European Parliament and of the Council as regards certain technical requirements for the donation, procurement and testing of human tissues and cells has been transposed to Cypriot legislation via Law 187(I)/2007 as regards the quality and security standards (donation, procurement, testing, processing, preservation,

[1] Diseases specific to people of Mediterranean origin, such as thalassaemia, a genetic blood disorder better known as Mediterranean anaemia.
[2] Further information is available at the website of the Cyprus Institute of Neurology and Genetics at http://srs.dl.ac.uk/arch/SESAME/cyprus/kyriakou/kyriakou.htm and at http://www.cing.ac.cy/

storage and distribution) of human tissues, cells and derivative products[3] and Commission Directive 2006/86/EC of 24 October 2006 implementing Directive 2004/23/EC is introduced into the Cypriot law via Regulations 438/2008 on the quality and security standards of human tissues, cells and derivative products (traceability, notification of serious adverse reactions and events, coding, processing, preservation,storage and distribution).[4]

Furthermore the implementing Directives of the European Blood Directive[5] are also transposed into the Cypriot legislation. Commission Directive 2005/61/EC of 30 September 2005 implementing Directive 2002/ 98/EC of the European Parliament and of the Council as regards traceability requirements and notification of serious adverse reactions and events as well as the Commission Directive 2005/62/EC of 30 September 2005 implementing Directive 2002/98/EC of the European Parliament and of the Council as regards Community standards and specifications relating to a quality system for blood establishments are transposed into the national legal framework via the amending law Law No. 10(I)/2007 on blood donation[6]. Commission Directive 2004/33/EC of 22 March 2004 implementing Directive 2002/98/EC of the European Parliament and of the Council as regards certain technical requirements for blood and blood components is transposed into national law via amending Law 3(I) /2006 as regards blood donation[7] and the amending Regulation 67/2006 on blood donation (collection,

[3] Law of 2007 as regards the quality and security standards (donation, procurement, testing, processing, preservation, storage and distribution) of human tissues, cells and derivative products. Legal act: Νόμος, number: N. 187(I)/2007; *Official Journal: Cyprus Gazette,* number: 4154, Publication date: 31/12/2007, Page: 01621-01714, Entry into force: 31/12/2007; Reference: (MNE(2008)50681). Originial text is published: Ο περί Προτύπων Ποιότητας και Ασφάλειας (Δωρεά, Προμήθεια, Έλεγχος, Επεξεργασία, Συντήρηση, Αποθήκευση και Διανομή) Ανθρώπινων Ιστών, Κυττάρων και Παράγωγων Προϊόντων Νόμος του 2007. Available in original language at: http://www.moh.gov.cy/moh/moh.nsf/All/AAE443D58AB42999C22575900039A2E6/$file/ιστών.pdf?OpenElement

[4] Legal act: Κανονισμοί, number: Κ.Δ.Π. 438/2008; *Official Journal: Cyprus Gazette,* number: 4318, Publication date: 05/12/2008, Page: 03533-03568, Entry into force: 05/12/2008; Reference: (MNE(2008)56589) Οι Περί Προτύπων Ποιότητας και Ασφάλειας Ανθρώπινων Ιστών, Κυττάρων και Παράγωγων Προϊόντων (Ιχνηλασιμότητα, Κοινοποίηση Σοβαρών Ανεπιθύμητων Αντιδράσεων και Συμβάντων, Κωδικοποίηση, Επεξεργασία, Συντήρηση, Αποθήκευση και Διανομή) Κανονισμοί του 2008. Available in original language at: http://www.moh.gov.cy/moh/moh.nsf/All/630D679F04A59F3AC22575900039BDBD/$file/kanonismoi.pdf?OpenElement

[5] Directive 2002/98/EC of the European Parliament and of the Council of 27 January 2003 setting standards of quality and safety for the collection, testing, processing, storage and distribution of human blood and blood components and amending Directive 2001/83/EC, OJ L 33, 8.2.2003, p. 30–40. Available at: http://eur-lex.europa.eu/Notice.do?val=283913:cs&lang=en&list=432018:cs,393196:cs,283913:cs,&pos=3&page=1&nbl=3&pgs=10&hwords=

[6] The (amending) Law of 2007 as regards blood donation. Legal act: Νόμος, number: N.10(I)/2007; *Official Journal: Cyprus Gazette,* number: N.10(I)/2007, Publication date: 16/02/2007, Page: 00217-00256, Entry into force: 16/02/2007; Reference: (MNE(2007)51693). In original language: Ο περί Αιμοδοσίας (Τροποποιητικός) Νόμος του 2007

[7] Legal act: Κανονισμοί, number: N.3(I)/2006; *Official Journal: Cyprus Gazette,* number: 4068, Publication date: 10/02/2006, Page: 00009-00029; Reference: (MNE(2006)51010). In original language: Ο περί Αιμοδοσίας (Τροποποιητικός) Νόμος του 2006.

security, testing and transfusion of blood)[8].

Law 138 (III)/2001 on the Processing of Personal Data (Protection of the Individuals) (Processing of Personal Data Law or Data Protection Act)[9] is also relevant in relation to the protection of data processing for personal data contained in biobanks. Since biobanks contain not only biological samples but also personal data about the donor of the biological material such as data related to health and genetic data, one of the most significant legal instruments on their regulations is the Protection of Personal Data Law which transposed Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data into national legislation in 2001.

The protection of data contained in biobanks provided by Law No. 138 (III) /2001 on the Processing of Personal Data shall be interpreted together with the Constitution of the Republic of Cyprus of 1960 (as amended in 1989, 1996, 2002 and 2006).[10]

While Article 11 of the Cypriot Constitution states that "Every person has the right to liberty and security of person", Article 15 sets forth that "every person has the right to respect of his private and family life". Article 17 of the Cypriot Constitution also provides that "every person has the right to respect for, and to the secrecy of, his [or her] correspondence and other communication, if such communication is made through means not prohibited by law".

In addition to the above the Law for Good Clinical Practice involving drugs for human use (Laws for 2001 until 2004)[11] is also important. A specific biobank related legislation, the Law No. 150(I) of 2001 on Providing for the Establishment and Function of the National Bioethics Committee (the so-called Bioethics Law) is also considered significant. The aforementioned Bioethics Law established the Cyprus National Bioethics Committee (CNBC), which was enacted in December 2001. The CNBC has adopted with very few changes the "Operational Guidelines for Ethics Committees that Review Biomedical Research" formulated by the World Health Organization, to form the

[8] Legal act: Κανονισμοί, number: Κ.Δ.Π. 67/2006; *Official Journal: Cyprus Gazette,* number: 4081, Publication date: 24/02/2006, Page: 00455-00473; Reference: (MNE(2006)51438). The Law has published in original language: Οι περί Αιμοδοσίας (Λήψη, Ασφάλεια, Έλεγχος και Μετάγγιση Αίματος) (Τροποποιητικοί) Κανονισμοί του 2006.

[9] The Processing of Personal Data (Protection of Individuals) Law 138(I)2001 as amended by The Processing of Personal Data (Protection of Individuals) (Amendment) Law of 2003 (37(I)2003). Available at: http://www.dataprotection.gov.cy/dataprotection/dataprotection.nsf/d1813d5911e138bdc2256cbd00313d1c/f8e24ef90a27f34fc2256eb4002854e7/$FILE/138(I)-2001_en.pdf In original language: Νόμος που τροποποιεί τον Περι Επεξεργασίας Δεδομένων Προσωπικού Χαρακτήρα (Προστασία του Ατόμου) Νόμο του 2001, αρ. 37(I)/2003. In original language available at: http://www.dataprotection.gov.cy/dataprotection/dataprotection.nsf/All/B708D98FB15F8D09C2256D9B0032AE61/$file/138(I)-2001&37(I)-2003.pdf?OpenElement

[10] Constitution of the Republic of Cyprus adopted on 16 Aug 1960, Unofficial translation in English is available at: http://www.cyprus.gov.cy/portal/portal.nsf/All/C44572D7363776ACC2256EBD004F3BB3?OpenDocument. In original language available at: http://www.kypros.org/Constitution/Greek/

[11] Legal act: Κανονισμοί; *Official Journal: Cyprus Gazette,* Publication date: 30/04/2004; Reference: (MNE(2004)59467) In original language published at: Οι περί Φαρμάκων Ανθρώπινης Χρήσης (Ορθή Κλινική Πρακτική) Κανονισμοί του 2004.

basis of the Operational Guidelines for Ethics Committees that Review Biomedical Research Involving Human Subjects in Cyprus, which were enacted in 2005 (Operational Guidelines).[12]

The ethical and scientific standards for carrying out biomedical research on human subjects have been developed and established in international guidelines, including the Declaration of Helsinki,[13] the CIOMS International Ethical Guidelines for Biomedical Research Involving Human Subjects,[14] and the WHO and ICH Guidelines for Good Clinical Practice. Compliance with these guidelines helps to ensure that the dignity, rights, safety, and well being of research participants are promoted and that the results of the investigations are credible. In the lack of specific regulation the establishment and operation of tissue banks in Cyprus were primary authorized by the guidelines issued by the below mentioned ethics committees.

It is also worthwhile to mention Law No. 1(I) of 2005 on the Safeguarding and Protection of Patients' Rights Law,[15] which provides enforceable legal provisions considering human rights in the field of health and, in particular, the right to life, the right to physical and mental integrity and security, the right to respect for private life and to dignified treatment in the provision of health services. The Law. No. 1 (I) 2005 sets out provisions on the right to protection of health through proper measures of prevention of diseases and health care, that are not regulated explicitly by other law.

Concerning the other important international legislations, it is also worth mentioning that the Convention on Human Rights and Biomedicine[16] was ratified by Cyprus and Article 38 of Law 31(III)/2001 on the Ratification of the European Convention on Human Rights and Biomedicine (Ratification Law) entered into force in 2002. Cyprus has also

[12] Operational Guidelines for the Establishment of Ethics Committees in Reviewing Biomedical Research Involving Human Subjects in Cyprus (Operational Guidelines,2005) enacted on 31. 3. 2005 (Κ.Δ.Π. 175/2005) Available at: http://www.bioethics.gov.cy/Law/cnbc/cnbc.nsf/All/74ACE403567F843EC2257 1C9002C3F3A/$file/EEBK000 UK Operational Guidelines.pdf In original language: Για τη Συσταση και Λειτουργια Επιτροπων Βιοηθικησ για τον Ελεγχο τησ Βιοιατρικησ Ερευνασ στην Κυπρο (Κ.Τ.Π 175/2005). Available in original language at:
http://www.bioethics.gov.cy/Law/cnbc/cnbc.nsf/All/521F178A5364E010C22571C9002C5199/$file/EEBK 000 Operational Guidelines_Greek.pdf

[13] World Medical Association Declaration of Helsinki on the Ethical Principles for Medical Research Involving Human Subjects Adopted by the 18th WMA General Assembly, Helsinki, Finland, June 1964. The current revision is available at: http://www.wma.net/e/policy/pdf/17c.pdf

[14] International Ethical Guidelines for Biomedical Research Involving Human Subjects. Prepared by the Council for International Organizations of Medical Sciences (CIOMS) in collaboration with the World Health Organization (WHO) CIOM, Geneva 2002. Available at:
http://www.cioms.ch/frame_guidelines_nov_2002.htm

[15] Law No. 1(I) of 2005 to provide for the safety and protection of patients' rights and for related matters. Dated 29 October 2004. (The Safeguarding and Protection of Patients' rights Law, 2004). Original text published in Episκme Ephκmerida tκs Kypriakκs Dκmokratias, 7 January 2005. Available at:
http://apps.who.int/idhl-rils/idhl/Cypr.05002.pdf

[16] 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 Oviedo, 4.IV.1997. Available at: http://conventions.coe.int/treaty/EN/Treaties/Html/164.htm

ratified the Convention for the Protection of Human Rights and the Dignity of Human Beings with regard to the Application of Biology and Medicine (Oviedo Convention) by Article 4 of the Law 31 (III)/2001. The Ratification Law also sets forth that the prohibited actions of the Convention or any activity that fails to comply with the provisions of the Convention shall be regarded as offences.[17]

Apart of the above mentioned pieces of legislation, the Private Medical Care Institutions (Control of Establishment and Operation) Law of 2001 is also relevant in the respective legal domain.[18]

3. ESTABLISHMENT AND MANAGEMENT OF BIOBANKS

As it is mentioned before the establishment and management of biobanks or tissue banks are not covered with special legislative framework in Cyprus.

Nevertheless it also has to be mentioned that the legal instruments in relation to the transplantation standards for the quality and safety of tissues and cells throughout the transplantation process are fully in compliance with the European standards and this is the area that is regulated the most thoroughly in the country. As it is mentioned above, Directive 2004/23/EC as regards traceability requirements, notification of serious adverse reactions and events and certain technical requirements for the coding, processing, preservation, storage and distribution of human tissues and cells is implemented via Regulations 438/2008 into Cypriot Law. The provisions of the Data Protection Act concerning the processing and storage of sensitive personal data is the most relevant regulative instruments that are applicable in the case of biobanks.

In relation to the establishment of biobanks Article 7 of the Protection of Personal Data Law also sets forth that the data controller is obliged to notify the Data Protection Commissioner[19] in writing about the establishment and operation of a filing system or the commencement of processing.

In relation to the collection and processing of personal data, the Article 2 of the Data protection Act also sets out that the 'personal data filing system' or 'filing system' means "any structured set of personal data which constitute

[17] Article 7 of Law 31 (III)/2001 also sets forth that the law allows research on embryos in vitro, if it ensures adequate protection of the embryo. The creation of human embryos for research purposes however is prohibited. Furthermore the infringement of article 14 of the Convention is an offence that is punished with imprisonment for up to two years and/or a fine up to CYP 5.000. In: Mathiessen-Guyader L, ed. Survey on Opinions from National Ethics Committees or Similar Bodies, Public Debate and National Legislation in relation to Human Embryonic Stem Cell Research and Use. Brussels, Belgium. European Commission Research Directorate-General, 2003.

[18] Law No. 90(I) of 2001 on Private Medical Care Institutions (Control of Establishment and Operation). See also Article 2 of Law No. 1(I) of 2005 to provide for the safety and protection of patients' rights and for related matters.

[19] The Data Protection Commissioner is responsible for monitoring the application of the Processing of Personal Data Law 2001 (see Article 18 Section (1)) Article 23 sets out the functions of the Commissioner. These include: b) to assist in the drawing up of codes of conduct; e) to report any contraventions of the law to the relevant authorities.; h) to conduct inquiries following complaints or on his own initiative http://www.dataprotection.gov.cy/dataprotection/dataprotection.nsf/index_en/index_en?opendocument

or may constitute the subject of processing and which are accessible according to specific criteria." While 'processing' or 'processing of personal data' means "any operation or set of operations which is performed by any person upon personal data, whether or not by automatic means, and includes the collection, recording, organization, preservation, storage, alteration, extraction, use, transmission, dissemination or any other form of disposal, connection or combination, blocking, erasure or destruction".

In the aforementioned notification the data controller shall state all the requirements as set forth in Article 7 Section (2) of the Data Protection Act, such as (a) the full name, business name or title and address of the data controller if the controller is not established in Cyprus, he or she must also state the full name, business name or title and address of his or her representative in Cyprus; (b) the address where the filing system is established; (c) a description of the purpose of the processing of the data which are or are intended to be included in the filing system; (d) a description of the category or categories of data subjects; (e) the categories of data which are or are intended to be processed or which are included or intended to be included in the filing system; (f) the period of time for which he or she intends to carry out the processing or to keep the filing system; (g) the recipients or categories of recipients to whom he or she communicates or may communicate the data; (h) the proposed transmissions of data to third countries and the purpose thereof; (i) the basic characteristics of the system and the measures for the security of the filing system or of the processing.

According to Article 7 Section (4) the Data Protection Commissioner is obliged to establish and maintain a Register of Filling Systems and Processing.

Nevertheless, the Protection of Personal Data Law provides a number of cases, where data processors are exempted from their obligation to notify the Data Protection Commissioner in order to process sensitive data. Therefore Article 7 Section (6) d) sets out that data processors are exempted from their obligation if the processing is performed by doctors or other persons who provide health services which concern medical data, provided that the controller is bound by medical confidentiality or other kind of confidentiality required by law or code of conduct and the data are neither transferred nor communicated to third parties.

However, persons who provide health services such as clinics, hospitals, health centres, recovery and detoxication centres, insurance funds and insurance companies as well as the controllers of personal data when the processing is performed in the framework of programs relating to telemedicine operations or provision of medical services through a network, are not excluded from this provision.

According to the Opinion of the Cyprus National Bioethics Committee regarding bioethical dilemmas of umbilical cord banking by private profit making companies adopted in 2004, "about 75% of cord blood banks are public or private non-profit banks, which offer a service for the benefit of the public. They store donated samples for the purpose of transplantation or research. They also store cord blood for family use in case of a known risk in a family with a rare HLA (human leuko-

cyte antigen) group."[20] The Opinion also sets out the CNBC's endeavour to emphasize publicly that the legislation should impose strict regulation and close supervision of the procedures (both in the public and the private domain) in relation to the services of cord blood banks and also to express that the protection of personal data of cord blood banks customers and their relatives, needs to be safeguarded.

4. PURPOSE AND SCOPE OF COLLECTION

According to Article 2 of the Data Protection Act, 'personal data' "means any information relating to a living data subject; whereas consolidated data of a statistical nature, from which the data subject cannot be identified, are not deemed to be personal data." The same provisions of the Act also set forth the definition of 'sensitive data', according to which it means data concerning racial or ethnic origin, political convictions, religious or philosophical beliefs, participation in a body, association and trade union, health, sex life and erotic orientation as well as data relevant to criminal prosecutions or convictions. In line with Article 2 of the Data Protection Act genetic information and other personal data based on genetic samples shall be deemed as sensitive personal data. Although Article 7 of the Data Protection Act provides that the collection and processing of sensitive data is prohibited, the collection of sensitive data is permitted when one or more of the conditions as set forth in Article 7 Section (2) are fulfilled.

The collection of sensitive data is permitted if e.g. (1) the data subject has given his or her explicit consent, unless such consent has been obtained illegally or is contrary to accepted moral values or a specific law provides that consent does not lift the prohibition; (2) processing is necessary so that the controller may fulfil his or her obligations or carry out his or her duties in the field of employment law; (3) processing is necessary to protect the vital interests of the data subject or of another person where the data subject is physically or legally incapable of giving his consent; (4) the processing relates solely to data which are made public by the data subject or are necessary for the establishment, exercise or defence of legal claims before the Court; (5) the processing relates to medical data and is performed by a person providing health services by profession and has a duty of confidentiality or is subject to relevant codes of conduct, on condition that the processing is necessary for the purposes of preventive medicine, medical diagnosis, the provision of care or the management of health-care services; (6) processing is necessary for the purposes of national needs or national security, as well as criminal and reform policy, and is performed by a

[20] Opinion of the Cyprus National Bioethics Committee (CNBC) regarding bioethical dilemmas of umbilical cord banking by private profit making companies, 2004. Available at: http://www.bioethics.gov.cy/Law/cnbc/cnbc.nsf/All/B5D91DC497A2EB49C2257308004B46B2/$file/Opinion of CNBC on bioethical dilemmas of umbilical cord banking by private profit making companies.pdf

service of the Republic or an Organisation or Foundation authorized for this purpose by a service of the Republic and relates to the detection of crimes, criminal convictions, security measures and investigation of mass destructions.

According to Article 4 of the Data Protection Act, the data controller shall ensure that the collected personal data are (a) processed fairly and lawfully; (b) collected for specified, explicit and legitimate purposes and are not further processed in a way incompatible with those purposes and (c) relevant, appropriate and not excessive in relation to the purposes of processing.

Taking into consideration the current practice on the processing and collection of personal data in the respective domain in Cyprus, the following databases are worthwhile to mention.

Cypriot National Genetic Database

The Cypriot National Genetic Database or Cypriot Disease National Database[21] (CNGD) is a repository of information about mutations leading to the inherited disorders in the Cypriot population. The CNGD is a National Mutation Frequency Database that provides comprehensive information on the observed frequency of disease-causing mutations in the Cypriot population. The Cypriot National Genetic Database results from the collaboration among several investigators from Erasmus Medical Center (The Netherlands) and Cyprus Institute of Neurology and Genetics (CING)[22] supported by the Human Genome Variation Society and co-financed by the European FP6 INCO grant MedGeNet[23] and by Asclepion Genetics in Switzerland.

Cyprus Institute of Neurology and Genetics

The Cyprus Foundation for Muscular Dystrophy Research is the parent organization of the Cyprus Institute of Neurology and Genetics. It was established in 1987 under the name Muscular Dystrophy Research Trust of Cyprus by the Cyprus Muscular Dystrophy patients' association (MDA Cyprus). In 1990 the Muscular Dystrophy Research Trust created the Institute and in 1995 the Trust was renamed as the

[21] The Cypriot National Genetic Database is online available at: http://www.goldenhelix.org/cypriot/

[22] Kypriako Idryma Erevnon Gia Ti Myiki Distrofia or in English, the Cyprus Institute of Neurology and Genetics (CING). Further information is available at: http://srs.dl.ac.uk/arch/sesame/cyprus/kyriakou/kyriakou.htm

[23] MedGeNet (Euro-Mediterranean Network for Genetic Services) is a project funded within the Specific measures in support of International Cooperation (INCO) in the 6th Framework Programme for Research and Technological Development of the European Union. The primary objectives of MedGeNet is to expand the human expertise in clinical genetics and cancer genetics in Mediterranean Partner Countries (MPC) through the transfer of knowledge and technology between the two rims of the Mediterranean which share a common burden of genetic diseases. Through the creation of a Euro-Mediterranean Network of Genetic Telecounselling and Telepathology consultation and advanced education for health professionals and medical staff, the MedGeNet Project will enable developing countries to share a diagnostic database and carry out distant diagnosis of genetic diseases with the help of international experts. More information is available on the project at:
http://cordis.europa.eu/fetch?CALLER=FP6_PROJ&ACTION=D&DOC=1&CAT=PROJ&QUERY=01230393a474:3659:1decd513&RCN=80006

Cyprus Foundation for Muscular Dystrophy Research. The Cyprus Institute of Neurology and Genetics (CING) provides specialized services and research in neurology, genetics, molecular biology, histopathology and virology. More specifically, the Institute is dedicated to preventing diseases through patient care, research and educational programmes on neurological and genetic conditions such as muscular dystrophy, multiple sclerosis, epilepsy, chromosomal abnormalities and all other aspects of molecular biology and genetics such as thalassaemia, molecular virology, mental retardation, cardiovascular disease, stroke, cystic fibrosis and neurogenetics.

Clinical Genetics Clinic

Clinical Genetics Clinic offers services to people affected by or who may be at risk of a genetic condition, which aim at the best possible quality of life and reproduction. At the Institute, the Clinical Genetics department carries out diagnostic assessment, management, treatment and genetic counselling for the whole spectrum of genetic conditions. This includes chromosomal aberration syndromes (e.g. Down syndrome, Williams syndrome), single gene disorders (e.g. achondroplasia, Marfan syndrome, neurofibromatosis), mitochondrial diseases, multi-factorial conditions (e.g. spina bifida) and prenatal exposure syndromes. The process of genetic counselling involves not only the exchange of information relating to the genetic disorder and relevant laboratory results but also supportive counselling. The clinical genetics team consists of a clinical geneticist and a genetic counsellor. Clinics are held both at the Institute and the Archbishop Makarios III hospital in Nicosia. Families are referred by a variety of health and other professionals as well as self-referrals. The department serves as a reference centre for the whole of the island. A genetic registry exists which is used for epidemiological data regarding the incidence and frequency of specific genetic disorders in Cyprus.

Bank of Cyprus Oncology Centre[24]

The Oncology Centre was founded in 1998 with the donation of the Bank of Cyprus and operates in Nicosia. The Bank of Cyprus Oncology Centre established a Medical Research Ethics Committee to consider applications for clinical trials to be carried out at the Centre in accordance with the Good Clinical Practice Guidelines. The Centre operates as an independent medical unit which is dedicated to provide services to cancer patients.[25]

5. PECUNIARY ASPECTS

In line with the Opinion of the Cyprus National Bioethics Committee (CNBC) regarding bioethical dilemmas of umbilical cord banking by private profit making companies, any financial re-

[24] Further information is available in Greek language at: http://www.bococ.org.cy/
[25] Information concerning the biobanks operating in Cyprus is based on the online database of the Privireal Project. Available at: http://www.privireal.org/content/rec/cyprus.php

ward to the individuals that participate in and donate biological samples for research programs, is generally prohibited. Cord blood haematopoietic stem cells are considered to be part of the human body and as such Article of 21 of the Oviedo Convention applies, stating that "the human body and its parts shall not, as such, give rise to financial gain ". Moreover, Article 2 of the Additional Protocol states that "The provisions of this Protocol applicable to tissues shall apply also to cells, including haematopoietic stem cells".

According to Article 17 of the Data Protection Act, the controller shall compensate a data subject who has suffered damage by reason of violation of any provision of this Law, unless he proves that he or she is not responsible for the event that caused the damage.

6. CONSENT

In accordance with Article 2 of the Data Protection Act, 'consent' "means the consent of the data subject, any freely given, express and specific indication of his or her wishes, clearly expressed and informed, by which the data subject, having been previously informed, consents to the processing of personal data concerning him or her."

Article 5 of the Act also provides that personal data may be processed only if the data subject has unambiguously given his consent to it. However, the personal data may be processed without the data subject's consent in case the processing is necessary (1) for compliance with a legal obligation to which the controller is subject; (2) for the performance of a contract to which the data subject is party, or in order to take measures at the data subject's request prior to entering into a contract; (3) in order to protect the vital interests of the data subject, (4) for the performance of a task carried out in the public interest or in the exercise of public authority vested in the controller or a third party to whom the data are communicated; (5) for the purposes of the legitimate interests pursued by the controller or by the third party to whom the personal data are communicated, on condition that such interests override the rights, interests and fundamental freedoms of the data subjects.

Consent of minors

According to Article 5(1) b) of Law No. 216 of 1990 on Relations of Parents and Children Law[26] the person who exercises parental care may take any necessary or legal steps in the interest of the child. The definition of parental care also provides with the same provisions according to which it includes the determination of the child's name, care of the child, administration of the child's property, and representation of the child in his or her personal and property relations. Law 216 of 1990 also declares parental care as a duty and a right exercised by both parents who are the representatives of the child in all litigation. Both parents' sig-

[26] Law 216 of 1990 on the Relations of Parents and Children

nature is required to indicate parental consent and to represent their minor children in conformity with the law.[27]

7. ACCESS TO DATA OR SAMPLES, AND ANONYMITY

With a view to the cross-linking of data, Article 8 of Law No. 138 (III)/2001 sets forth that the combination of filing systems is permitted only in accordance with the conditions referred to in Articles 5 and 8 of the Data Protection Act.

Article 8 provides that every combination shall be notified to the Data Protection Commissioner by a statement submitted jointly by the data controllers or by the controller who will combine two or more filing systems which have different purposes. If at least one of the filing systems which are to be combined contains sensitive data or if the combination results in the disclosure of sensitive data or if the combination to be carried out a single code number is to be used, the combination is permitted only with the prior license of the Data Protection Commissioner and shall be issued in accordance with a prescribed form on payment of the prescribed fees. In addition to the above, the approval of Data Protection Commissioner for the combination of two or more filing systems is subjected to an administrative proceeding, during which the data controllers shall provide information on the purpose for which the combination is considered necessary; the category of personal data to which the combination relates; the period of time for which the combination is permitted; and any terms and conditions which may be imposed in order to protect the rights and liberties, especially the right to privacy of the data subjects or third parties.

Both the statements made under Article 8 of the Act, as well as the copies of the licence for combination, shall be filed in the Register of Combinations, kept and maintained by the Data Protection Commissioner.

Article 9 of the Protection of Personal Data Law lays down the relevant provisions on the processing of personal data to third parties that is subjected to the adequate level of protection available at the respective country of the recipient. The relevant provisions of the Protection of Personal Data Law set forth that transmission of data which have undergone processing or are intended for processing after their transmission to any country shall be permitted after a license of the Commissioner. The Commissioner shall issue the license only if he or she considers that the said country ensures an adequate level of protection. For this purpose, he or she shall take into consideration the nature of the data, the purposes and duration of the processing, the relevant general and special rules of law, the codes of conduct and the security measures for the protec-

[27] There was no parental authority in former Cypriot legislation in line with the (Article 4 and 6 of Cap 277) Greek Civil Code, according to which solely the father had the right to guardianship. On the parents' joint representation see also Vathrakokolis, The New Family Law (1990) at p. 584, Stylioanon v Stylianon (1988) 1 CHR 520, Civil Appeal 7835, 9 October 1988 in which Supreme Court adopted the approach exclaimed by that author (In: Andreas Neoclous & Co., *Introduction to Cyprus Law,* Limassol, Cyprus, 2000. Available at: http://www.neocleous.biz/en/download/ebook/neobook.pdf)

tion of data, as well as the level of protection in the countries of origin, transmission and final destination of the data.

The transmission of personal data to a country which does not ensure an adequate level of protection, is permitted exceptionally after a license of the Commissioner, where one or more of the conditions are fulfilled as set forth in Article 9 Sections (2)-(3). The transmission is permitted if the data subject has given his or her consent to the transmission or the transmission is necessary in order to protect the vital interests of the data subject, or for the conclusion and performance of a contract, or for the implementation of precontractual measures which have been taken in response to the data subject's request. The transmission is also permitted if it is necessary in order to deal with an exceptional necessity for the safeguard of a superior public interest, especially for the performance of conventions of co-operation with the public Authorities of the other country or for the establishment, exercise or defence of legal claims before a Court.

The Data Protection Commissioner may also allow the transmission of data to a country which does not ensure an adequate level of protection, provided that the controller provides sufficient guarantees for the protection of privacy and fundamental liberties and the exercise of relevant rights and such guarantees may result from appropriate contractual clauses.

Article 10 of the Data Protection Act also sets out that the processing of data is confidential. It shall be carried out only by persons acting under the authority of the controller or the processor and only upon instructions from the controller.

Articles 11-12 set forth the basic rights of the data subject to the access of his or her data. The controller shall, at the time of collection of the personal data from the data subject, provide the latter, in an appropriate and explicit way, with at least the following information:

(a) its identity and the identity of its representative, if any and
(b) the purpose of the processing.

The controller shall also inform the data subject on

(a) the recipients or the categories of recipients of the data;
(b) the existence of the right of access to and rectification of the data and
(c) whether the data subject is obliged to provide assistance, the provisions setting out this obligation, and the consequences of his or her refusal, if any, provided that this notification is necessary for securing in each case the legitimate processing.

However, Article 11 Section (4) also declares that the obligation to inform under subsections (1), (2) and (3) may, on the application of the controller, be waived wholly or partly, by decision of the Commissioner in case the collection of personal data is performed for the purposes of defence, national needs or national security of the Republic or for the prevention, detection, investigation and prosecution of criminal offences.

Article 12 of the Data Protection Act sets out the legal provisions concerning

I.) Information on the personal data relating to the data subject that are or were processed: (1) all the personal data relating to him or her which

have undergone processing, as well as any available information as to their source; (2) the purposes of the processing, the recipients or the categories of recipients, as well as the categories of data which are or are to be processed; (3) the progress of the processing since his or her previous briefing; (4) the logic which every automated process of data in relation to the data subject, is based.

II.) The rectification, erasure or blocking of the data, the processing of which has not been performed in accordance with the provisions of the Data Protection Act, especially due to inaccuracies or shortages.

III.) The notification to third parties, to whom the data have been communicated, of every rectification, erasure or blocking which is done as it is stated above in point II), unless this is impossible or it requires disproportionate efforts.

8. STORAGE

According to Article 4 of the Data Protection Act, the data controller shall ensure that the collected personal data are accurate and, where necessary, kept up to date. The data collector is also obliged to keep the collected data in a form which permits identification of data subjects for no longer than is necessary, in the Data Protection Commissioner's discretion, for the fulfilment of the purposes for which they were collected and processed.

After the expiry of this period, the Commissioner may, by a reasoned decision, allow the preservation of personal data for historical, scientific or statistical purposes if he or she considers that the rights of the data subjects or third parties are not affected.

The data controller shall also be responsible for the destruction of personal data which have been collected or which are further processed in contravention of the provisions of data collection for historical, scientific or statistical purposes. If the Commissioner ascertains, either on his own initiative or following a complaint, that the destruction of personal data has not been accomplished, he or she shall order the interruption of the collection or processing and the destruction of the personal data already collected or processed.

9. SUPERVISION, COMPENSATION, PENALTIES

The Ministry of Health and the National Health Authority operate as overall supervisory authorities in relation to the establishment and operation of human tissue banks or databases.

Furthermore, the Human Tissue Authority[28] is established under the Director of Medical Services at the Ministry of Health and regulates the safety of human tissues in accordance with EU Directives 2004/23/EC, 2006/ 86/EC and 2006/17/EC. The Authority operates as the licensing and supervisory

[28] Further information is available at:
http://www.moh.gov.cy/moh/moh.nsf/All/6EBB7741AA4C7359C225759000389FF4?OpenDocument
[29] Information concerning the Bioethics Committees operating in Cyprus is based on the online database of the Privireal Project. Available at: http://www.privireal.org/content/rec/cyprus.php

authority in relation to the establishment and operation of tissue banks.

Besides the aforementioned governmental bodies the operation of bioethics committees ensured the the review of legal, social and ethical issues that arisen in the domain of human tissues and transplantation.

There are four ethics committees in Cyprus[29]. The first one is operated within the framework of the Pancyprian Medical Association, the second is established by the Bank of Cyprus Oncology Centre and the Cyprus Institute of Neurology and Genetics is also engaged in managing an ethical committee and lastly the National Bioethics Committee was established by the Bioethics Law and has been operated since October 2002. The National Bioethics Committee discusses bioethical issues and publishes its opinions to the public, it can consider issues that it tables on its own agenda, or that are proposed by the Ministry of Health, the Parliament or the public. The National Bioethics Committee consists of 13 members who are appointed by the Council of Ministers.

It also has to be noted, that Law No. 150(I) of 2001, the so-called Bioethics Law on the Establishment of the Bioethics Committee sets forth the legal definition of bioethics. According to Bioethics Law "'bioethics' means the study of ethical, deontological, social, humanistic and legal problems that emerge from the use of modern biotechnology, biology, medicine, genetics and pharmaceutics but mainly they are caused by human intervention on the biological procedure and on the human genotype based on the precautionary principle and the promotion of health."

The above mentioned Operational Guidelines also provides detailed regulations on the establishment and management of ethics committees including their composition and operation in Cyprus. The Guidelines also sets out that independently from the follow-up procedures of a program by an ethics committee, the Cyprus National Bioethics Committee has the right, whenever it considers necessary and/or appropriate within its terms of reference, to proceed with its own investigations on the ethical evaluation of any program and take any decisions it deems appropriate for the reviewed program. Within these lines, the Cyprus National Bioethics Committee has the right to modify, suspend, terminate or to confirm the initial decision of an ethics committee. The decision of the Cyprus National Ethics Committee is final and binding to all parties.

Pancyprian Medical Association[30]

The Pancyprian Medical Association is responsible for the approval of proposals for medical research proposals.

Cyprus National Bioethics Committee

The Cyprus National Bioethics Committee (CNBC) was established by the Parliament in April 2000. The thirteen members of the Committee are appointed by the Council of Ministry of Health for a period of four years and may be re-appointed for a second four-year term. The members of the CNBC

[30] http://www.cyma.org.cy/

are responsible for considering proposals for biomedical research and making recommendations to researchers according to the Helsinki Declaration.[31]

The National Bioethics Committee – if possible – is composed of 4 members from the sociology or anthropology disciplines, 4 members from the medical or biological disciplines and 4 members from any discipline, who have been acknowledged in the country for their acclaimed work. The CNBC is established by Law No. 150(I) of 2001 on the establishment and operation of the National Bioethics Committee.[32] The Cyprus National Bioethics Committee is an independent body and is not subject to the administrative control of any ministry, independent officer, department or service and has the powers stipulated by the Law No. 150(I) of 2001 Law providing for the Establishment and Function of the National Bioethics Committee or any other Law (Article 3 Section (2)). The Bioethics Committee is operated with particular regard for the conduct of research that may affect the physical and mental condition of the patient, the environment and animals. The CNBC determines ethical standards or policies for research with human beings and reviews the ethical aspects of research projects. Anyone may submit an application to the National Bioethics Committee who intends to conduct a clinical trial. All clinical trials are authorized to begin only upon approval by the National Bioethics Committee and the National Health Authority (so called Medicines Council or Pharmaceutical services). Nevertheless, there is no procedural interaction between the two authority during the approval process.

The Cyprus National Bioethics Committee has adopted with very few changes the "Operational Guidelines for Ethics Committees that Review Biomedical Research"[33] formulated by the World Health Organization, to form the basis of the operational guidelines for the establishment of ethics committees in reviewing biomedical research involving human subjects in Cyprus.

The CNBC has been adopted the following opinions as part of its duty.

- Opinion of the Cyprus National Bioethics Committee on choosing a future child´s sex using the preimplantation genetic diagnosis (PGD) method (2006)
- Palliative Care (2008)
- Genetically Modified Organisms (2008)

[31] World Medical Association Declaration of Helsinki on the Ethical Principles for Medical Research Involving Human Subjects. Adopted by the 18th WMA General Assembly, Helsinki, Finland, June 1964. Available at: http://www.wma.net/e/policy/b3.htm

[32] Law No. 150(I) of 2001 on the establishment and operation of the National Bioethics Committee (Law of 2001 on bioethics (establishment and operation of the National Bioethics Committee)). Original text published in Episκmκ Ephκmerida tκs Kypriakκs Dκmokratias, Part I, 14 December 2001, No. 3558, pp. 1159 et seq.) Available at: http://www.bioethics.gov.cy/Law/cnbc/cnbc.nsf/All/C2E546EBAEB075EDC2 2571C9002BE3A1/$file/The Bioethics Establishment and Function of the National Bioethics Committee Law - English Translation.pdf

[33] The Operational Guidelines for the establishment of ethics committees in reviewing biomedical research involving human subjects in Cyprus which were enacted on 31.3.2005 (Κ.Δ.Π. 175/2005) is available at: http://www.bioethics.gov.cy/Law/cnbc/cnbc.nsf/All/0CEAB26AC17DB109C22571C9002D8EE0/$file/EE BK000 UK Operational Guidelines.pdf

- Predictive health information for insurance purposes (2008)
- Opinion of the Cyprus National Bioethics Committee regarding bioethical dilemmas of umbilical cord blood banking by private profit making companies (2004)
- Prenuptial test for thalassaemia before the conclusion of a civil wedding in Cyprus (2008)
- Opinion of the Cyprus National Bioethics Committee on Medically Assisted Human Fertilization (2007)

In accordance with the aforementioned operational guidelines Law 150 (I)/2001, the Committee formed three Review Bioethics Committees the Members of which are appointed for a period of two years:

I. The Review Bioethics Committee for Biomedical Research on Human Beings and their biological substances that review protocols relating to biomedical research on human beings and their biological substances,
II. The Review Bioethics Committee for the clinical trials on Medicinal Products of Human Use and
III. The Review Bioethics Committee for Biomedical Research on Human Being and their biological substances and the clinical trials on Medicinal Products of Human Use that review protocols relating to medical devices applied on human beings.

The Role of the Review Bioethics Committees is to contribute to safeguarding the dignity, rights, safety and well-being of all actual or potential research participants. In order to fulfil their duty the Committees provide independent review of the ethical aspects of proposed studies and is responsible for carrying out the review of research proposals before the commencement of the research.

The CNBC monitors, directs, coordinates, and reviews the work performed by the above three Review Bioethics Committees.

Medical Research Ethics Committee of the Bank of Cyprus Oncology Centre

The Bank of Cyprus Oncology Centre is an independent legal entity registered as a Charity under the Charities Law, Cap. 41. The Bank of Cyprus Oncology Centre established a Medical Research Ethics Committee to consider applications for clinical trials to be carried out at the Centre in accordance with the Good Clinical Practice Guidelines. The Committee, which was established based on the Guidelines of the Royal College of Physicians of London and the Code currently used by the Greek National Ethics Committee, operates according to the principles set out in the Helsinki Declaration. The Department of Pharmaceutical Services of the Ministry of Health in Cyprus is informed whenever a study is approved and takes place at the Centre.

Ethics Committee of the Cyprus Institute of Neurology and Genetics

The Ethics Committee of the Cyprus Institute of Neurology and Genetics (CING)[34] was established in 1994 by the

[34] Further information is available at: http://srs.dl.ac.uk/arch/sesame/cyprus/kyriakou/kyriakou.htm

Scientific Council of the Institute, the first of its kind in Cyprus. The aim of the Committee is to review research projects carried out at CING involving human subjects and/or samples, which now require the Committee's approval. The Ethics Committee adopted and performs its duties in line with the provisions of the Helsinki Declaration and the European Union's guidelines on good clinical practice. The Cyprus Government provides the Institute with an annual grant towards the services provided to the public health sector (government hospitals). The Institute also has an agreement with the government for the provision of forensic services.

10. PUBLIC DEBATE

In 'Social values, Science and Technology' (Special Eurobarometer 225/ Wave 63.1) respondents were asked: 'How important do you think protecting information about our private life from misuse and exploitation will be for our society in ten years time?'. In all countries, a majority believes that protecting such information is very important. Similarly in Cyprus, 76 % thinks it is very important and 17 % believes it is fairly important.

The Cyprus National Bioethics Committee (CNBC), at a meeting on 31 October 2006 considered an article published on the internet reporting that, couples from Sweden come to Cyprus in order to perform Preimplantation Genetic Diagnosis (PGD) so as to choose the sex of their future child. The CNBC adopted its opinion on Choosing a future child's sex using the Preimplantation Genetic Diagnosis (PGD) method[35] and emphasizes in its opinion that according to Article 14, of the Oviedo Convention "the use of techniques of medically assisted procreation shall not be allowed for the purpose of choosing a future child's sex, except where serious hereditary sex related disease is to be avoided" .

In 2008, after its six years of operation, the National Bioethics Committee submitted its request again for a decent amount of state support for covering its management and activities. Although, the Bioethics Consultative Committee was established in 2002 by Law No. 150(I) of 2001, the budget approved by the Health Ministry was described as insufficient.[36]

[35] Opinion of the Cyprus National Bioethics Committee on the Choosing a future child's sex using the Preimplantation Genetic Diagnosis (PGD) method. Adopted in Nicosia, 31 October 2006. Available at: http://www.bioethics.gov.cy/Law/cnbc/cnbc.nsf/All/180DFD1206CF2D06C22573090021A032/$file/OPINION OF THE CYPRUS NATIONAL BIOETHICS COMMITTEE CHOICE OF SEX.pdf

[36] http://www.cyprus-mail.com/news/main.php?id=42065&cat_id=1

II. FORENSIC BIOBANKS

1. DEFINITION OF FORENSIC BIOBANKS

Although there is no legal definition for forensic databases in the Cypriot legislation, according to Article 6 of the Personal Data Protection Act, the collection and processing of sensitive data, is permitted for the interest of criminal investigation.

It also has to be noted that despite past violence and the consequent division of the country to Northern Turkish and Southern Greek Cypriot regions, statistics for the Republic of Cyprus point to a crime rate that is lower than that of most other western European countries. A crime rate of 6.44 crimes per 1,000 inhabitants[37] shows a low incidence of crime in Cyprus. Although, there is a low crimes rate in Cyprus, the cases of missing persons in relation to inter-communal fighting as well as in connection to the events of July 1974[38] and the period afterwards are considered to be the most relevant field for the usage of forensic databases and services.

2. RELEVANT LAWS

Since there is no specific legal instrument for the regulation of forensic databases, the National Database operates under the scope of the Protection of Personal Data Law. Thus the relevant provisions of the Protection of Personal Data Law are also applicable to forensic databases and the collection of genetic information in Cyprus for investigating purposes. Apart of the above mentioned provisions set forth in the Protection of Personal Data Law, the Criminal Code (1962-L-72604), the Evidence Law of 1994 (Chap. 9, N. 94 (I)/94) and its Regulations are worth mentioning. In relation to the duties of the police the Police Law, Law No. 73(I.) 2004 and the General Police Regulations (No. 51/89) have to be noted.

Furthermore, it should be mentioned that the Cypriot Police Force is operated under the guidance of the Code of Police Ethics which is based on the European Code of Police Ethics, adopted by the committee of Ministers on 19 September 2001 at the 765th Meeting of the Ministers' Deputies of the Council of Europe, Strasbourg.

3. ESTABLISHMENT OF FORENSIC BIOBANKS

The establishment and maintenance of forensic biobanks (such as forensic laboratories and databases) are carried by the police on the basis of the Personal Data Protection Law. There are three institutions that are worthwhile to mention in relation to the provision of forensic services and the maintenance of forensic databases in Cyprus: the so-called Criminalistic Services operated at the Police Headquarters, the State General Laboratory and finally the Laboratory of Forensic Genetics

[37] Further data is available at: http://www.country-data.com/cgi-bin/query/r-3616.html
[38] The Turkish invasion in Cyprus launched on 20 July 1974. Further information is available at the website of the Committee on Missing Persons in Cyprus http://www.cmp-cyprus.org/nqcontent.cfm?a_id=1343&tt=graphic&lang=l1

(LabFoG) of the Cyprus Institute of Neurology and Genetics. The National Database was established in 1998 and its managed by the Cyprus Police Headquarters in close collaboration with the Laboratory of Forensic Genetics of the Cyprus Institute of Neurology and Genetics. The database contains genetic profiles, name and surname of the donor, information on IDs and the donor's passport number.

The searches for matching profiles can be asked on the basis of crime stains, convicted individuals or missing persons. In addition to the above in the report of a match, the sample numbers, date of entry of the profiles and the DNA samples are provided to the requester.[39]

Criminalistic Services

The Criminalistic Services (CSCP), situated at the Police Headquarters, is the main provider of forensic science support to the Criminal Justice system of the Republic of Cyprus. The Criminalistic Services was founded in 1950. At the early stages, its five-member personnel provided only fingerprint expertise. Since Cyprus Independence in 1960, CSCP is the major provider of professional forensic science services to support the Police, the judicial investigation and the prosecution of crime in the island. Any exhibits requiring examinations of forensic parameters that are not covered in the Services are forwarded to other Organisations in Cyprus, with which excellent co-operation has been established, (Institute of Genetics, Governmental General Lab, Geological Dept, Nicosia General Hospital, Veterinary Services) or to laboratories operated abroad. The Criminalistic Services consist of seven labs that carry out forensic examinations on fingerprints, firearms, toolmarks, shoemarks, trace evidence, forged documents, counterfeit currency and crime scene work in serious cases.[40]

State General Laboratory

The State General Laboratory (S.G.L.) has been developed to control, monitor and apply research and operate as an advisory services centre for the public sector, recognized at local, national and European level. It is the official Government Laboratory fulfilling the requirements embodied in the laws pertaining to the chemical, biological/microbiological and toxicological industry in Cyprus, operating as a national control centre of foodstuff, pharmaceuticals, narcotics and police exhibits.

The State General Laboratory comprises 19 laboratories. Each laboratory is specialized and dedicated to its own area of work. The function and scope of each laboratory is stated in its own Quality Manual, which is a part of the SGL's Quality Assurance System. The Laboratory No.3 is the Forensic Chemistry And Toxicology Laboratory accredited according to ISO/IEC/EN 17025 (formerly ISO Guide 25 & EN45001 on the General Requirements for the Competence of Calibration and Testing Laboratories). The General State Laboratory has supervisory authority over the Forensic Chemistry and Toxicology Laboratory.

The aim of the Forensic Chemistry and Toxicology Laboratory (No. 3) is to provide reliable analytical data in an impartial and objective way. The Physical Sciences Forensic Laboratory trace evidence analy-

[39] Information is based on DNA Databases to Assist with Criminal Investigations, Replies to the Questionnaire on National DNA Databases, Council of the European Union Brussels, 16 June 2006
[40] http://www.police.gov.cy/police/police.nsf/dmldept5_en/dmldept5_en?OpenDocument

sis (paint/fibres/glass/plastics), perform analysis of inks and paper, examination of hairs (for species identification), chemical restoration of erased numbers on metallic surfaces, blood, semen stains identification (K.M. test / A. P. test) and visiting serious scenes of crime for specialized taking samples.

The laboratory covers the forensic areas of illegal drugs and psychotropic substances, arson, explosives and explosive residues, criminal traces. As a forensic toxicology service it covers the analysis of blood alcohol, illegal drugs/psychotropic substances, drugs, pesticides, carbon monoxide and other poisons. It also covers chemicals/metals in biological samples. Applied research is implemented in cases of method development and/or where further analytical investigation of certain cases can enhance the gathering of evidence as well as facilitate justice in the judicial process. The laboratory staff provides expert witness testimony for courts concerning examinations conducted by the laboratory after official request by summons. Credibility, honesty and impartiality followed by the ability to transfer scientific evidence and opinion to court are the aims of the laboratory. Its activities cover exchanging forensic science knowledge with Forensic Laboratories in Europe and USA for combating crime and participating in the sharing of information on illegal/psychotropic substances through an official channel established by the Drug Enforcement Agency (USA) for controlling their abuse and trafficking. The laboratory carries out gunshot residue analysis with the Electron Microscope on samples taken from the hands, clothes etc. of suspects. These analyses concern serious cases of murder, shootings, suicides etc.

The aim of the Forensic Science and Toxicology Laboratory is to provide reliable laboratory data and to give impartial and objective scientific expert witnessing in court, to support the police, law enforcement authorities as well as international efforts in the fight against crime, drug trafficking and terrorism. Also, its assistance to forensic coroners in unnatural death investigations as well as its role in assisting with emergency hospital poisoning cases is of vital importance. The laboratory covers the following areas of activity: Analysis of narcotics and psychoactive substances. Analysis of exhibits from crime scenes involving arson, explosives and other trace evidence. Analysis of biological samples for the determination of alcohol, narcotics and psychoactive drugs, pesticides, carbon monoxide, heavy metals and other poisons.

Cyprus Institute of Neurology and Genetics

The Institute also has an agreement with the government for the provision of forensic services and plays a key role in the fight against crime by providing specialized DNA services to the police authorities and expert court testimony for criminal and civil investigations. The Institute provides services, as requested, to all doctors, clinics, hospitals, lawyers and the Police Authorities.

According to the website of the Committee of Missing Persons in Cyprus,[41] the Laboratory of Forensic Genetics (LabFoG) of the Cyprus Institute of Neurology and Genetics in Nicosia is responsible for carrying out the Genetics phase (DNA analysis and matching) of the CMP (Committee of Missing Persons) project.[42] According to Article 7 of the Terms of Reference of the Committee on Missing Persons in Cyp-

[41] http://www.cmp-cyprus.org/nqcontent.cfm?a_id=1&tt=graphic&lang=l1
[42] http://www.cmp-cyprus.org/nqcontent.cfm?a_id=1316&tt=graphic&lang=l1

rus:[43] "The Committee [on Missing Persons in Cyprus] shall look only into cases of persons reported missing in the intercommunal fighting as well as in the events of July 1974 and afterwards."[44]

4. SAMPLES AND SAMPLE TAKING, CONSENT

According to Article 6 of the Data Protection Act, processing of sensitive data is prohibited, unless the processing is necessary for the purposes of national needs or national security, as well as criminal and reform policy, and is performed by a service of the Republic or an Organisation or Foundation authorized for this purpose by a service of the Republic and relates to the detection of crimes, criminal convictions, security measures and investigation of mass destructions.

The police are allowed to take a sample from minors if the legal guardian consents or upon court order. In the latter case, the court shall take the legal guardian's position and the case circumstances into account. The same requirements are also valid for mentally ill persons with the additional condition that a medical advice is needed.[45]

5. PURPOSE AND SCOPE OF COLLECTION

Beside the provisions sets out under Article 4 of the Protection of Personal Data Law, Article 35-36 of the Police Ethic Code repeat the regulations on the legal boundaries of collecting, processing and storing of personal data. The Police Ethics Code provides that the police is allowed to interfere with an individual's right to privacy when it is strictly necessary and only to obtain a legitimate objective. Additionally Article 36 sets forth that the collection, storage and use of personal data by the police is carried out in accordance with the Protection of Personal Data Law (Law No. 138/(I) 2001) and international data protection principles. In particular, this is limited to the extent necessary for the performance of lawful, legitimate and specific purposes.

The police can only coercively sample a crime suspect upon court order. Otherwise, written consent of the suspect is needed. A sample can be taken from a convicted offender as soon as he or she has been sentenced. There are no restrictions to the collection of crime scene stains[46].

6. ACCESS TO DATA AND SAMPLES

The request for obtaining information from the National Database must be submitted through the Cyprus Police Headquarters and the Director of the Laboratory of Forensic Genetics is entitled to grant access to the information stored in the database. Solely the Director of the Laboratory of Forensic Genetics and the personnel (e.g. staff members) are authorized by the

[43] Terms of Reference on the Establishment of the Committee on Missing Persons in Cyprus, 1981. Available at: http://www.cmp-cyprus.org/media/attachments/CMP/CMP docs/Terms_of_Reference_1981.pdf

[44] As a result of the violence generated during those times, a total of 502 Turkish Cypriots and 1493 Greek Cypriots were officially reported as missing by both communities to the Committee on Missing Persons in Cyprus (CMP).

[45] Information is based on N. van Camp, et al., *National Forensic DNA Databases in the EU,* European Ethical-Legal Papers N°9, Leuven, 2007. pp. 39-40.

[46] Information is based on N. van Camp, et al., *National Forensic DNA Databases in the EU,* European Ethical-Legal Papers N°9, Leuven, 2007. pp. 39-40.

Director to have access to the National Database.[47]

Considering the usage of cross-linking data, Article 8 of Law No. 138 (III)/2001 sets forth that the combination of filing systems is permitted only in accordance with the conditions referred to in Article 5 and Article 8 of the Data Protection Act. Furthermore, Article 24 Section (1) of Protection of Personal Data Law provides the Data Protection Commissioners duty on keeping the Registers as set out in the Act. Article 24 Section (1) e) stipulates that the Commissioner is obliged to maintain a 'Register of Confidential Filing Systems', in which there shall be recorded, after an application of the controller and a decision of the Commissioner, the filing systems kept by the Ministers of Justice and Public Order and Defence and the Public Information Office, for purposes of national security or the detection of particularly serious crimes. Combinations with at least one such filing system shall also be filed in the Register of Confidential Filing Systems. According to the Protection of Personal Data Law, the Registers set out in Article 24 Section (1) a)-d) shall be accessible to every person, however the access to the Register of Confidential Filing Systems is limited and subjected to the approval of the Data Protection Commissioner.

With a view to the right of access to personal data, as it is set forth in Article 12 of the Data Protection Act, the Act also declares, that by a decision of the Commissioner, on application by the controller, the obligation to inform the data subject in line with Article 12 Sections (1)-(2) may be waived, wholly or partly, where the processing of personal data is performed for purposes relating to national needs or to the national security of the Republic or for the prevention, investigation, detection and prosecution of criminal offences. Considering the international cooperation, DNA profiles can be exchanged with other EU Member States through Interpol contact points. Furthermore the cooperation agreements of Cyprus and all Interpol member countries allow mutual consultation of DNA databases and exchange of profiles.

7. STORAGE

The DNA profiles of crime suspects collected for police purposes have to be removed from the database when no charges have been filed against them or upon their acquittal. Nevertheless the DNA profiles of convicted offenders has to be retained indefinitely unless the person's criminal record is cleared according to the Re-establishment Act. The DNA profiles that are derived from unidentified crime scene stains are retained on the database until they are identified. Although DNA samples of crime suspects can be retained up to the stage of court hearing or until the completion of an investigation, if no charges are filed or the person is not sentenced by the court, the DNA sample has to be removed from the database. The DNA samples of convicted offenders are retained indefinitely unless the person's criminal record is cleared according to the Re-establishment Act.[48]

[47] Information is based on N. van Camp, et al., National Forensic DNA Databases in the EU, European Ethical-Legal Papers N°9, Leuven, 2007. pp. 39-40.
[48] N. van Camp, et al., National Forensic DNA Databases in the EU, European Ethical-Legal Papers N°9, Leuven, 2007. pp. 39-40.


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