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THE LEGAL REGULATION OF BIOBANKS

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GeneBanC

CENTER FOR ETHICS AND LAW IN BIOMEDICINE
CEU

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

In the framework of 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 second in the series of country reports prepared by CELAB.

In order to ease the work and map the legal situation a questionnaire has been sent out to all Member States. We are grateful to Professor Penelope Agallopoulou, Professor emeritus at the University of Piraeus, Greece for filling the related questionnaires and for providing useful insights into the regulatory framework of classical and forensic biobanks in Greece.

Budapest, 1 May, 2009

I. CLASSICAL AND POPULATION BIOBANKS

1. DEFINITION OF BIOBANKS

Greece has not established special legislation for the regulation of biobanks. As a consequence, these are governed via a complex web of generally applied constitutional provisions, laws, regulation, codes of practice, guidelines and so forth, each of which potentially applies to biobanks.

The term 'biobank' has not been officially defined in Greek law. However, several discrete definitions have been given. The National Bioethics Commission defines biobanks as "any collection of human biological material [...] The biological specimens may include tissues, cells, blood or DNA isolated from [the donors] and may have been collected for medical or educational or research purposes by public or private agencies."[1] It is important to mention that the regulation of biobanks gets more complex and raises more legal and ethical concerns when, in the context of biobanks, the biological material collected is linked to personal information of the donor.

2. REGULATION

As it was already mentioned, Greece has not enacted tailored legislation concerning biobanks. The existing collections are regulated via generally applied legal provisions. As a consequence, the regulation of biobanks seems to be rather complicated and incoherent. Additionally, given the special nature of biobanks and of the data contained, traditional legislation often proves to be inefficient to meet novel technological challenges.

Biobanks contain not only biological samples, but also personal data of the individuals, whose specimens have been collected, such as data related to health and genetic data. As a consequence, one of the principal legal instruments concerning their regulation is Act 2472/97 on the Protection of Individuals with Regard to the Processing of Personal Data implementing the European Directive 95/46/EC on the Protection of Individuals with Regard to the Processing of Personal Data and on the Free Movement of Such Data.[2]

[1] National Bioethics Commission, '*Recommendation on Banks of Biological Material of Human Origin (Biobanks) in Biomedicine Research',* available at:
http://www.bioethics.gr/media/pdf/recommendations/biobanks_recom_eng.pdf.. In original language:
Εθνική Επιτροπή Βιοηθικής, «*Εισήγηση για τις Τράπεζες Βιολογικού Υλικού (Βιοτράπεζες) Ανθρώπινης Προέλευσης στη Βιοϊατρική Έρευνα»,*
http://www.bioethics.gr/media/pdf/recommendations/biobanks_recom_gr.pdf
This definition has been also adopted by several academics. See for example Mitrou L., Maniatis G., *The Protection of Genetic Data* (Athens, Thessaloniki: Sakkoulas Publication, 2008) p. 22. In original language: Μήτρου Λ., Μανιάτης Γ., *Η Προστασία των Γενετικών Δεδομένων* (Αθήνα, Θεσσαλονίκη: Εκδόσεις Σάκκουλα, 2008) σ. 22.

According to Article 2 of Act 2472/97 data that relate to health are considered to be sensitive. Genetic data are deemed to be sensitive as well, but there is no explicit reference to them in Article 2. Some academics support the view that the definition of health data encompasses genetic data too,[3] while other suggest that they should be protected as sensitive because they reveal racial or ethnic origin.[4] In Opinion 115/2001 rendered by the Hellenic Data Protection Authority, it is suggested that, in light of the current legislation, genetic examination for employment purposes should be permitted only under specific conditions and provided that certain safeguards have been enacted.[5] Having that in mind, it could be inferred that genetic data form an over-sensitive category of personal data due to their special nature.

Article 7(1) of Act 2472/97 establishes a general prohibition on processing sensitive data. The processing of such data can take place only under the conditions laid down by Article 7 (2). As it is explicitly referred to, prior permission by the Hellenic Data Protection Authority is a precondition for the collection and the processing of sensitive data. Article 7A provides the cases where such authorization is not required, but biobanks do not fall within any of these exceptions.

The protection of the data contained in biobanks provided by Act 2472/97 should be read in conjunction with the Greek Constitution. More specifically, Article 9 of the Greek Constitution protects private (and family) life. The scope of the protection conferred by Article 9 is wide and is not only confined to the protection of the sanctuary of home, but also applies to the majority of the aspects that compose the private sphere of an individual's life. This article combined with Article 5 (1) that protects the free development of one's own personality and Article 2 (1) that provides the protection of individual dignity covers almost every activity within the context of the private life of an individual.[6]

However, during the constitutional revision of 2001, Article 9A was inserted in the Greek Constitution. According to this provision, all persons have the

[2] As it was amended by Act 3471/2006 and Act 3625/2007. In original language N.2472/97 «Προστασία του Ατόμου από την Επεξεργασία Δεδομένων Προσωπικού Χαρακτήρα». Available at: http://www.dpa.gr/pls/portal/docs/PAGE/APDPX/ENGLISH_INDEX/LEGAL%20FRAMEWORK/LAW%202472-97-MARCH08-EN.PDF

[3] Armamentos P, Sotiropoulos V., *Personal Data. Interpretation of the Act 2472/97* (Athens-Thessaloniki, Edition Sakkoulas, 2005),p37. In original language: Αρμαμέντος Δ.Π., Σωτηρόπουλος Α. Β., *Προσωπικά Δεδομένα. Ερμηνεία Ν.2472/1997* (Αθήνα-Θεσσαλονίκη, Εκδόσεις Σάκκουλα ΑΕ, 2005), σ. 37.

[4] D. I. Igglezakis, *Sensitive Personal Data. The Processing of Special Categories of Personal Data and its Consequences* (Athens, Thessaloniki: Sakkoulas Publication, 2004). In original language: Ιγγλεζάκης Δ. Ι., Ευαίσθητα Προσωπικά Δεδομένα. Η Επεξεργασία Ειδικών Κατηγοριών Προσωπικών Δεδομένων και οι Συνέπειές της (Αθήνα, Θεσσαλονίκη: Εκδόσεις Σάκκουλα, 2008) σ. 22

[5] Hellenic Data Protection Authority, Opinion 115/2001 on processing employees' personal data. In original language: Οδηγία 115/2001 για την επεξεργασία δεδομένων των εργαζομένων διαθέσιμη στο: http://www.dpa.gr/portal/page?_pageid=33,23367&_dad=portal&_schema=PORTAL

[6] T. Garanis-Papadatos, D. Boukis, 'Report on Data Protection Act 2472/97 in Greece, in D. Beyleveld, D. Townend, S. Rouille-Mirza and J. Wright (eds.), *Implementation of the Data Protection Directive in Relation to Medical Research in Europe* (Aldershot: Ashgate Publishing, 2004), p. 142.

right to be protected with regard to the collection and the processing of their personal data as provided by law. Data protection was already provided directly by Act 2472/97 and indirectly via the combination of the existing constitutional Articles, as referred. Nevertheless, this new Article is of great utility as it differentiates the level of protection provided, especially when the right for data protection is in conflict with rights and interests (constitutional or statutory) of third parties or public interest.[7]

Additionally, in 2001, another provision was introduced. Article 5 (5) provides that "all persons shall enjoy full protection of their health and genetic identity." Two non-conflicting interpretations have been stressed with regard to this article. According to the first, it aims to protect genetic informational self-determination. According to the second, the individual shall have the right to control his or her genes forming his or her genetic identity and to oppose against any alteration of them without his or her free will.[8] The utility of this provision has been the object of many academics' criticism, as it is estimated that genetic identity was efficiently protected via general constitutional provisions. As a consequence, the introduction of Article 5 (5) may lead to interpretive problems in regard to the scope of general constitutional rights and provisions, such as the right of free development of one's personality (Article 5 (1)), the right to the protection of someone's life (Article 5 (2)) and the provision concerning the protection of individual dignity (Article 2 (1)). [9]

Furthermore, two more constitutional provisions can be applied with regard to biobanks and their relation to the state. These are Article 21 (3) that refer to the social right of the protection of citizens' health and Article 25 (1) that sets the state as custodian of all fundamental rights.[10]

Apart of the above mentioned pieces of legislation, Act 2071/92 referring to the modernization and organization of the health system, is also to be kept in mind, when it comes to the regulation of biobanks.[11] More specifically, Article 43 of said Act lays down the rights of hospital patients.

Act 3418/2005, the so-called 'Code of Medical Ethics' also proves to be very important. Given the sensitivity of the data contained in biobanks, confidentiality is considered to be a safeguard of great significance. For that reason, special reference should be made to Articles 13 and 14 that comprise doctors' legal obligation of confi-

[7] Ev. Mallios, *The human genome. Genetic research and protection of human rights* (Athens, Komotene: Ed. N. Sakkoulas, 2004) p. 148-154. In original language: Μάλλιος Ευ., *Το Ανθρώπινο Γονιδίωμα . Γενετική Έρευνα και Προστασία των Δικαιωμάτων του Ανθρώπου (Αθήνα, Κομοτηνή, Εκδόσεις Αντ. Ν. Σάκκουλα, 2004)* σ. 148-154.

[8] *Ibid* p. 156-157.

[9] *Ibid* p. 154-160.

[10] National Bioethics Commission, '*Report on Banks of Biological Material of Human Origin (Biobanks) in Biomedicine Research'*, available at: http://www.bioethics.gr/media/pdf/reports/biobanks_rep_eng.pdf. In original language: Εθνική Επιτροπή Βιοηθικής, «*Εισήγηση για τις Τράπεζες Βιολογικού Υλικού (Βιοτράπεζες) Ανθρώπινης Προέλευσης στη Βιοϊατρική Έρευνα», http://www.bioethics.gr/media/pdf/recommendations/biobanks_recom_gr.pdf*

[11] In original language: Ν. 2071/92 «Εκσυγχρονισμός και Οργάνωση Συστήματος Υγείας».

dentiality. Doctors' confidentiality is also required by the Greek Penal Code.[12] More specifically, Article 371 of the Greek Penal Code on violation of professional confidence aims to protect the confidentiality of information obtained for professional reasons. Pecuniary sanctions or imprisonment are imposed to the professionals who disclose information or facts that have come to their knowledge while practising their profession.

A specific biobank-related piece of legislation is Act 3305/2005 that sets the legal framework of collections of biological material established for the purposes of medical assisted reproduction.[13] According to this Act, a presidential decree shall provide the details concerning the function of the said biobanks. Unfortunately, such a decree has not yet been issued – a fact that renders the Act practically inactive. Also in Article 6 of Act 2723/99 on transplantations of tissues and organs there is a brief reference to the competent authorities to set the regulatory framework concerning cryopreservation biobanks of tissues.[14]

In sum, Greek legislation lacks a tailored legal framework for the regulation of biobanks. So far, no relevant legislative attempt has been made, with the exception of Act 3305/2005 that, as mentioned *supra*, remains inactive in practice. Nevertheless, it should be mentioned that in 2006 the National Commission of Bioethics has issued a recommendation with regard to the regulation of biobanks.[15] According to the opinion issued by the Commission the major ethical issue raised by biobanks is the relationship between personal autonomy and social solidarity. The Commission considered the public health benefits justify the operation of biobanks. Also, in 2007 another recommendation was issued by the Commission concerning umbilical cord blood banking. [16]

3. ESTABLISHMENT AND MANAGEMENT OF BIOBANKS

Greek legislation does not provide any special procedure for the establishment and management of biobanks. However, according to Article 7 (1) of Act 2472/97, in order to collect and process sensitive personal data and to establish and run a database that

[12] In original language: Άρθρο 371 Π.Κ. «Παραβίαση Επαγγελματικής Εχεμύθειας»
[13] In original language : N. 3305/2005 «Εφαρμογή της Ιατρικώς Υποβοηθούμενης Αναπαραγωγής»
[14] In original language: N. 2723/99 «Μεταμοσχεύσεις Ανθρωπίνων Ιστών και Οργάνων και Άλλες Διατάξεις»
[15] National Bioethics Commission, '*Recommendation on Banks of Biological Material of Human Origin (Biobanks) in Biomedicine Research'*, available at: http://www.bioethics.gr/media/pdf/recommendations/biobanks_recom_eng.pdf. In original language: Εθνική Επιτροπή Βιοηθικής, «*Εισήγηση για τις Τράπεζες Βιολογικού Υλικού (Βιοτράπεζες) Ανθρώπινης Προέλευσης στη Βιοϊατρική Έρευνα»*, *http://www.bioethics.gr/media/pdf/recommendations/biobanks_recom_gr.pdf*
[16] National Bioethics Commission, *Opinion on Umbilical Cord Blood Banking,* available at http://www.bioethics.gr/media/pdf/recommendations/opinion_uc_eng.pdf. In original language: Εθνική Επιτροπή Βιοηθικής, «*Γνώμη για τις Συλλογές Ομφαλοπλακουντιακού Αίματος»*, http://www.bioethics.gr/media/pdf/recommendations/opinion_uc_gr.pdf

would contain sensitive data, prior authorization by the Data Protection Authority is required. Given the fact that a number of sensitive personal data are processed in the context of biobanks, such authorization would be necessary for the establishment of biobanks.

Article 7A of Act 2472/97 provides a number of cases, where data processors are exempted from their obligation to notify the Data Protection Authority and to obtain authorization by the latter in order to process sensitive data. However, biobanks do not fall within any of these exceptions.

Act 3305/05 that sets the regulatory framework of clinics – and of the relevant cryopreservation banks – designed for medical assisted reproduction purposes establishes also the National Authority of Medical Assisted Reproduction.[17] According to Article 20, one of the competences of the Authority is to oversee whether the clinics comply with the provisions of the Act and whether they fulfill the standards required for granting the authorization for establishment. The Authority has been set up in December 2005. However, as it is pointed out in the latest report of the Authority, its aims have not been adequately fulfilled so far, due to lack of funding and personnel.[18]

In addition, Article 6 of Act 2737/99, provides that for the setting up of biobanks of human tissues earmarked for transplantation, a ministerial decision of the Minister of Health and Social Solidarity is required.[19]

4. PECUNIARY ASPECTS

According to Greek legislation, for fear of inducement, any financial reward to the individuals that participate in and donate biological samples for research programs, is generally prohibited. This is also the case for the donors of tissues and organs. However Article 11 of Act 2737/99 provides that donors[20] might be compensated in case of disability or death, caused by the removal of the tissue or organ or for the costs incurred in relation to the preparatory medical examinations that take place before the removal.

5. CONSENT

Biobanks contain both biological samples and personal data, some of which are sensitive. For that reason, two kinds of consents should be requested. The individuals who give samples to be stored in biobanks should consent not only to the collection of their biological material, but also to the collection and processing of their sensitive personal data.

Specifically, any intervention on the human body is considered to be intrusive, therefore it can affect the

[17] In original language: Εθνική Αρχή Ιατρικώς Υποβοηθούμενης Αναπαραγωγής (Ε.Α.Ι.Υ.Α), βλ. http://www.iya.gr

[18] Annual Report of 2007 of the National Authority of Medical Assisted Reproduction published in December 2008, available in original language at: http://www.iya.gr/index.cfm/doc/12/cat/7

[19] In original language: Υπουργείο Υγείας και Κοινωνικής Αλληλεγγύης, βλ. http://www.mohaw.gr

[20] Or in case of death of the donor, that occurred due to complication during or as a result of the removal of the tissue or organ, his or her relatives shall be compensated, as provided by law.

right to self-determination as well as bodily autonomy and integrity. Articles 2 (1), 5 (1) and 7 (2) of the Greek Constitution protect human dignity and the free development of one's personality and also prohibit causing bodily harm. Thus, any collection of biological samples without the prior consent of the person for whom the specimen is collected, however benevolently, is *prima facie* unlawful and unconstitutional.[21,22]

Also, according to Article 308 of the Greek criminal law, causing bodily harm, without consent, constitutes a criminal assault.[23] It has been pointed out that this provision aims to protect not only the human body, but also one's right to bodily integrity, that is one's right to make decisions with regard to his or her body.[24]

Additionally, Article 12 of Act 3418/2005 on the 'Code of Medical Ethics' provides that doctors are not allowed to perform any medical intervention without the prior informed consent of the patient. For transplantations, Article 12 of Act 2737/1999 provides that consent of the donor should be given in written form. However, it is also provided that in cases where a person has not given his or her consent to be a donor, but has neither expressed any refusal, the removal of tissues and organs might take place, provided that the spouse, the adult descendants, the parents or the brothers or sisters of the deceased person do not oppose to the given removal.

Consent should be the aftermath of a freely made decision. Autonomous decision-making requires that the individuals, from whom biological samples are to be collected, have been provided with all the necessary information in order to make informed choices about themselves (informed consent). According to Article 11 of Act 3418/2005 on the 'Code of Medical Ethics', patients should be given all the necessary information with regard to the risks and the benefits of any proposed medical procedure so that they can make a free decision and, as a consequence, give their informed consent.

Also, according to Article 5 of Act 2472/97, consent is one of the conditions under which personal data should be processed to meet the requirement of fair and lawful processing set in the first principle of Article 4 of the Act. The concept of consent is defined in Article 2 (ia) as *'any freely given, explicit and specific indication of will, whereby the data subject expressly and fully cognizant signifies his or her informed agreement to personal data relating to him or her being processed. Such information shall include at least information as to the purpose of processing,*

[21] Ev. Mallios, *The human genome. Genetic research and protection of. human rights* (Athens, Komotene: Ed. N. Sakkoulas, 2004) pp. 182-184. In original language: Μάλλιος Ευ., *Το Ανθρώπινο Γονιδίωμα . Γενετική Έρευνα και Προστασία των Δικαιωμάτων του Ανθρώπου (Αθήνα, Κομοτηνή, Εκδόσεις Αντ. Ν. Σάκκουλα, 2004)* σ. 182-184.

[22] Different views have been expressed exclusively for cases where biological material needs to be collected within the context of criminal procedure, for the detection of serious crimes.

[23] In original language: Άρθρο 308 Π.Κ., Απλή Σωματική Βλάβη.

[24] N. Androulakis, *Criminal Law. The General Part, II* (Edition Ant. N. Sakkoulas, 1986) p. 45. In original language: Ανδρουλάκης Ν., *Ποινικό Δίκαιο, Γενικό Μέρος, ΙΙ* (Εκδόσεις Αντ.Ν Σάκκουλας, 1986) σ. 45.

the data or data categories being processed, the recipients or categories of recipients of personal data as well as the name, trade name and address of the controller and his or her representative, if any. Such consent may be revoked at any time without retroactive effect'. It has been pointed out that the Article defines consent as 'freely given' in order to underline the fact that it should be both voluntary and not been given under undue pressure.[25]

As it is already mentioned, biobanks contain *inter alia* medical and genetic data. For the purposes of the Greek data protection legislation, health and genetic data are sensitive data. Article 7 (1) of Act 2472/97 provides for a general prohibition on the processing of sensitive data. However, the blanket restriction of Article 7 (1) is waived under a number of conditions provided in Article 7 (2),[26] first of which is the written consent of the data subjects.[27] Article 7 (2) a), introduces an additional requirement to the consent in comparison to Article 5: the former provision requires that consent be given in a written form.

It is worth mentioning that, as provided by Article 4 (1) a), personal data should be processed for specified, explicit and legitimate purposes. However, in the biobank context, it is doubtful whether the purposes of processing could be specified and explicit. Most of the research biobanks came into existence in the framework of research projects that intent to last for

[25] T.Garanis-Papadatos, D. Boukis, 'Report on Data Protection Act 2472/97 in Greece, in D. Beyleveld, D. Townend, S. Rouille-Mirza and J. Wright (eds.), *Implementation of the Data Protection Directive in Relation to Medical Research in Europe* (Aldershot: Ashgate Publishing, 2004), p. 152.

[26] Article 7 (2). Exceptionally, the collection and processing of sensitive data, as well as the establishment and operation of the relevant file, will be permitted by the Authority, when one or more of the following conditions occur:

a) The data subject has given his/her written consent, unless such consent has been extracted in a manner contrary to the law or *bonos mores* or if law provides that any consent given may not lift the relevant prohibition.

b) Processing is necessary to protect the vital interests of the data subject or the interests provided for by the law of a third party, if s/he is physically or legally incapable of giving his/her consent.

c) Processing relates to data made public by the data subject or is necessary for the recognition, exercise or defence of rights in a court of justice or before a disciplinary body.

d) Processing relates to health matters and is carried out by a health professional subject to the obligation of professional secrecy or relevant codes of conduct, provided that such processing is necessary for the purposes of preventive medicine, medical diagnosis, the provision of care or treatment or the management of health-care services.

e) Processing is carried out by a Public Authority and is necessary for the purposes of aa) national security, bb) criminal or correctional policy and pertains to the detection of offences, criminal convictions or security measures, cc) protection of public health or dd) the exercise of public control on fiscal or social services.

f) Processing is carried out exclusively for research and scientific purposes provided that anonymity is maintained and all necessary measures for the protection of the persons involved are taken.

g) Processing concerns data pertaining to public figures, provided that such data are in connection with the holding of public office or the management of third parties' interests, and is carried out solely for journalistic purposes. The Authority may grant a permit only if such processing is absolutely necessary in order to ensure the right to information on matters of public interest, as well as within the framework of literary expression and provided that the right to protection of private and family life is not violated in any way whatsoever.

[27] Article 7 (2) a) of Act 2472/97

several decades and aim to offer resources to a number of distinct research purposes. As a consequence, the creators of these databases are not always able to specify the exact research purposes of the projects at the very beginning. Taking this into account, it is disputable whether the condition of data subject's consent, as it is provided by Articles 5 and 7 (2) a), could be exercised.

The seven conditions laid down in Article 7 (2) seem to be open alternatives and it does not occur by the wording of the Article that any of them has a lexical priority, i.e. the processing can take place provided that at least one of the conditions is fulfilled However, in a biobank context, where health-related data are processed and in light of what has been mentioned above about the importance of consent prior to any intervention on the human body, it is disputable whether, when consent is impracticable or inappropriate, meeting one or another of the conditions will suffice.

In the absence of special legislation, consent of people with limited legal capacity is regulated according to general provisions. According to Article 127 of the Civil Code, "anyone who has completed his eighteenth year is an adult and has the capacity for any juridical act." Anyone that is under the age of eighteen is considered to be minor. Minors under the age of ten, lack legal capacity completely (Article 128), while those between the age of ten and eighteen are of limited legal capacity (Article 129)[28].

Mental, psychological and physical health are also determining factors in terms of legal capacity. Article 1666 et seq. of the Civil Code provides that a person can be deprived of his or her legal capacity when she or he is totally or partially unable to take care of his or her affairs on his or her own, due to a psychiatric or mental disorder or physical disability. This is also the case for adults who due to addiction might place themselves, their spouses and a key circle of relatives in peril. The Greek Civil Code provides three possible forms of guardianship; 'private judicial support', 'auxiliary judicial support' and 'combined judicial support'. The latter form is a combination of the two former. According to that third form, the judge, having taken into consideration the particular circumstances of each case, specifies the legal acts that persons may carry out on their own separating these from the ones where the approval of their guardian is required.[29]

Article 10 of Act 2737/1999 provides that tissue and organ donation is permitted provided that the donor is adult. Exceptionally, the removal of bone marrow is allowed from minors too, under a number of cumulative conditions: the recipient should be a brother or sister of the donor, the donor must be compatible with the recipient, the removal should be considered to be necessary for the life of

[28] I. Kriari-Catranis, Rights of Embryo and Foetus in Public and Private Law, available at: http://www.bioethics.org.gr/Embryokriari.doc

[29] United Nations Enable – Rights and Dignity of Persons with Disabilities, *Progress of efforts to ensure the full recognition and enjoyment of the human rights of persons with disabilities – Report of the Secretary-General [A/58/181],* available at: http://www.un.org/disabilities/default.asp?id=148

the recipient, there should be no other compatible donor with full legal capacity available and both parents should give consent. Minors who have completed their twelfth year should also consent to the removal. According to the mentioned provision, the removal of tissues and organs from a living donor is permitted only to individuals who are not under private judicial support and are capable of giving consent.

Additionally, as provided by Act 3418/2005 on the 'Code of Medical Ethics' one of the conditions of valid consent concerns the legal capacity of the patient to give consent. Specifically it is provided that where the patient is a minor, consent is to be obtained by those who exercise the parental care or the rights of custody. However, the minor's opinion shall be taken into consideration, where, to the doctor's belief, the former is mature enough to realize the state of his or her health, the proposed medical procedure and the consequences, results and risks deriving from the procedure in question. In cases where the patient is incapacitated, consent must be provided by the patient's judicial guardian, if any, or by the relatives of the patient.

6. ACCESS AND ANONYMISATION

As it was referred to above, one of the conditions for processing personal data is consent. According to the definition given in Article 2 (ia), the data subject shall provide his or her consent after being informed at least as to the purpose of processing, the data or data categories being processed, the recipients or categories of recipients of personal data as well as the name, trade name and address of the controller and his or her representative, if any. Therefore, a third party could have access to biobanks only under the condition that the initial consent comprises the potential of having the donor's personal data accessed by the third party. In any other case, third parties should obtain the consent of the data subject in order to be authorized to access.

As the use and processing of genetic data by third parties is crucial in the field of research activities, it can certainly be seen as a burden on scientific activities that an express authorization is needed for the use of materials and information stored in biobanks. Anonymisation is being regarded as a solution to this problem. The advantages of such a technique is that it safeguards the protection of data subjects, while at the same time it waives the obligation of compliance with the data protection legislation when processing anonymised data.[30] For the purposes of Article 2a of Act 2472/97, 'personal data' shall mean any information relating to the data subject. After being anonymised, data are non-personal and thus their protection is not within the scope of the Act.

It is noteworthy that the Act does not specify in which cases data should be anonymised, with one exception. One of the conditions of lawful processing of sensitive data, laid down in

[30] R. Jay and A. Hamilton, *Data Protection Act and Practice* (London: Sweet & Maxwell, 2003), pp 426-27.

Article 7 (2) (f), is that any processing carried out exclusively for research and scientific purposes is allowed, provided that anonymity is maintained and all the necessary measures for the protection of the persons involved are taken.[31]

Neither is the term 'anonymisation' defined. It could be inferred from Article 2 c) that data are rendered anonymous when their data subject is no longer identifiable. Yet, it is not clear when a person is identifiable. Recital 26 of the European Data Protection Directive 95/46/EC (that is implemented by the Act 2472/97), provides that when determining the 'identifiable person', account should be given to 'all the means likely reasonably to be used either by the controller or by any other person to identify the said person.' It is argued though, that the interpretation of the word 'reasonably' might be rather problematic.[32] In the Greek context, Opinion 136/2001 of the Hellenic Data Protection Authority offers an indicative example of what could be deemed as 'anonymisation' by the Authority.[33] It has been considered to be legal for therapeutic communities and for the Greek Police to send data concerning epidemiological factors to the National Documentation and Informational Centre so as to cover the need for documentation on a national and European level, provided that these data have been anonymised through coding.[34]

Processing anonymous data is deemed to pose minimal threat to data subjects' privacy. However under certain circumstances, anonymisation might violate individual's privacy. It is debatable whether the right of control, which stems from the right to informational self-determination, is not affected by granting access to anonymised data for further purposes, in relation to which the data subject is likely to have ethical concerns.[35]

It should be mentioned that authorization by the Data Protection Authority for processing – and thus also for providing access to – sensitive personal information is always required.[36] In that sense, even when such data derive from already existing collections, in order to be provided access to third parties, not only re-consent of the subject is required, but also authorization by the Data Protection Authority. This rule also applies to scenarios where data are anonymised. In such cases the obligation to obtain the data subject's consent is waived, but not the requirement for authorization by the Authority.

[31] In original language: Άρθρο 7παρ. 2 εδ. στ του Ν. 2472/97.
[32] C. M. R. Casabona, 'Anonymisation and Pseydonymisation: The Legal Framework at a European Level' in D. Beyleveld, D. Townend, S. Rouille-Mirza and J. Wright (eds.), *The Data Protection Directive and Medical Research Across Europe* (Aldershot: Ashgate Publishing, 2004)
[33] See *Annual Report of 2001* of the Hellenic Data Protection Authority. Available in Greek at: http://www.dpa.gr/pls/portal/docs/PAGE/APDPX/ANNUALREPORTS/AR2001/DPA_ANNUAL_REPORT_2001.PDF
[34] The code consisted from the date of birth of the subject, the third letter of the name of his or her father and mother. Number '1' was used to indicate males, while number '2' to indicate females.
[35] D. Beyleveld, 'Data Protection and Genetics: Medical research and the Public Good' (2007) 18 *King's Law Journal*, p. 282.
[36] The definition of 'processing', as provided by Article 2d of Act 2472/97, is rather broad and includes – among others – allowing access.

Article 16 (1) of the Greek Constitution regarding freedom of research is also to be taken into consideration when it comes to the right of accessing data contained in biobanks. Hindering access should be confined only in cases where data protection reasons arise. Therefore, the prohibition set in Article 7 (1) of Act 2472/97 shall be interpreted in conjunction with the constitutional provisions of Article 16 (1) (freedom of research) and Article 25 (1) (principle of proportionality).

In conclusion, Article 7 (2) e) provides that, among other conditions, processing of sensitive data is permitted when it *'is carried out by a public authority and is necessary for the purposes of aa) national security, bb) criminal or correctional policy and pertains to the detection of offences, criminal convictions or security measures, cc) protection of public health or dd) the exercise of public control on fiscal or social services*'. As a consequence access to data contained in biobanks may be provided to public authorities. In such a case the consent of the data subject is not required. However, prior permission by the Data Protection Authority needs to be obtained. It is noteworthy, that the provision refers to criminal or correctional 'policy' and not to 'purposes.' This has been criticised as being blur and enhancing an interpretation that may lead to widening the scope of the provision.[37]

7. STORAGE

In the Greek legislation, there is no special provision on how to store biological material in a biobank. An exception is Presidential Decree No 26/2008, that incorporates the European Directive 2004/23/EC.[38,39] The Decree regulates the standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells. Article 10 and Annex VII of the decree regulate, amongst others, how cells and tissues should be stored.

The storage of personal information contained in biobanks is regulated by Article 10 of Act 2472/97. The aim of the provision is to ensure the confidentiality and security of processing personal data. Article 10 (3) provides that *'the Controller must implement appropriate organisational and technical measures to secure data and protect them against accidental or unlawful destruction, accidental loss, alteration, unauthorised disclosure or access as well as any other form of unlawful processing. Such measures must ensure a level of security appropriate to the risks presented by processing and the nature of the data subject to processing...'* It is also mentioned that the Authority shall offer instructions and issue regulations to indicate the level of security required for each category of data and processing. The Authority suggests data con-

[37] P. Armamentos, V. Sotiropoulos, *Personal Data. Interpretation of the Act 2472/97* (Athens-Thessaloniki, Edition Sakkoulas, 2005), p. 241. In original language: Αρμαμέντος Δ.Π., Σωτηρόπουλος Α. Β., *Προσωπικά Δεδομένα. Ερμηνεία Ν.2472/1997* (Αθήνα- Θεσσαλονίκη, Εκδόσεις Σάκκουλα ΑΕ, 2005), σ. 241.

[38] Directive 2004/23/EC of the European Parliament and of the Council of 31 March 2004 on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells.

[39] In original language: Προεδρικό Διάταγμα 26/2008 - ΦΕΚ 51/Α'/24.3.2008.

trollers to adapt and submit Security Plans and Disaster Recovery and Contingency Plans, especially when processing of sensitive data takes place.[40]

8. SUPERVISION, COMPENSATION, PENALTIES

Unfortunately in Greece, there is no supervisory authority especially tailored for biobanks. Of course, the Data Protection Authority supervises the compliance with the data protection legislation. Also, as it as already referred to, the National Authority of Medical Assisted Reproduction is competent to oversee whether the clinics comply with the provisions of Act 3305/05 regarding medical assisted reproduction. However the Authority has been blamed of malfunctioning due to lack of funding and personnel. The absence of a supervising Authority specifically for biobanks makes the regulation and the control of biobanks even more difficult.

9. PUBLIC DEBATE

Biobanks magnetize the interest of a considerable part of the scientific community. However, public debate regarding the legal, ethical and social issues that biobanks raise has not taken place yet.

[40] See (in original language):
http://www.dpa.gr/portal/page?_pageid=33,23529&_dad=portal&_schema=PORTAL

II. FORENSIC BIOBANKS

In Greece no forensic biobank exists. Article 200A (1) of the Code of Criminal Procedure provides that DNA analysis can be ordered when there are serious indications that a person has committed felony by use of force, crimes against sexual liberty of another person, or acts aiming at the creation of or the participation in a criminal organization as defined by Article 187 of the Greek Penal Code. DNA analysis also might be asked by the suspect so as to prove his or her innocence.

As it is provided by Article 200A, when the analysis of DNA is negative and thus the innocence of the accused person is proven, both the biological sample and the genetic fingerprint shall be destroyed.[41] Should the opposite turn out to be the case, albeit the sample shall be destroyed right after the analysis, the genetic fingerprints are maintained for the purposes of the criminal procedure. However, after the irrevocable ending of the trial, genetic fingerprints shall also be destroyed.

Opinion 15/2001 of the Data Protection Authority regarding genetic printing is worthy to be referred.[42] The Opinion has been rendered by the Authority in the view of drafting a bill concerning the fight against organized crime. The Authority underlines the special nature of genetic data and points out that they shall be collected and processed, in compliance with the conditions set in Article 7 of Act 2472/97 regarding the processing of sensitive data. Additionally, it underlines the risks that the processing of genetic data may entail, as it may lead to social stigmatization and exclusion[43].

Potential social benefits are also recognized by the Authority. DNA analysis is thought to be a useful tool for the detection of serious crimes. However, the analysis for such purposes should be confined to the non-coding part of

[41] Under genetic fingerprints information deriving from the analysis of the DNA is meant also in Greek terminology.

[42] In original language: ΑΠΔΠΧ, Γνωμοδότηση 15/2001 «Οδηγία για την ανάλυση γενετικού υλικού με σκοπό την εξιχνίαση εγκληματικών πράξεων». Available in original language at: http://www.dpa.gr/pls/portal/docs/PAGE/APDPX/LAW/NOMOTHESIA%20PROSOPIKA%20DEDOMENA/401_2001.DOC

[43] T. Garanis-Papadatos, D. Boukis, 'Report on Data Protection Act 2472/97 in Greece, in D. Beyleveld, D. Townend, S. Rouille-Mirza and J. Wright (eds.), *Implementation of the Data Protection Directive in Relation to Medical Research in Europe* (Aldershot: Ashgate Publishing, 2004), p. 154.

the DNA and in any case the creation of personality profiles shall be strictly prohibited. Also the Authority insists that the innocence of the suspects should be principally detected via other means available and that the DNA analysis shall be seen as the ultimate remedy. It is also pointed out that the legislation regarding genetic printing shall make explicit reference to the criminal offence for the detection of which DNA analysis is permitted. Given the intrusive nature of genetic printing, such a method shall be applied exclusively for the detection of serious crimes and, in any case, application for preventive purposes should be ruled out. In conclusion, the Authority underlines that importance should be given to the obligation to destroy genetic material after the identification of the person, or the proof of innocence of the suspect.

Genetic fingerprints are already used by the law enforcement authorities for the detection of serious crimes.[44] In addition, in an attempt to fight against organized crime, there have been certain considerations concerning the establishment of a database containing genetic fingerprints. However, the potential of establishing a forensic biobank is not welcomed by several academics, who point out that the DNA analysis within the context of legal procedures shall aim exclusively at the identification of a person. Thus the storage of the biological material collected, falls out of the scope of this aim.[45]

[44] See Article 200A of the Criminal Procedure Code.

[45] See L. Mitrou, G. Maniatis, *The Protection of Genetic Data* (Athens, Thessaloniki: Sakkoulas Publication, 2008) p. 50. In original language: Μήτρου Λ., Μανιάτης Γ., *Η Προστασία των Γενετικών Δεδομένων* (Αθήνα, Θεσσαλονίκη: Εκδόσεις Σάκκουλα, 2008) σ. 50; National Bioethics Commission, Decision for the Use of Genetic Fingerprints in the Criminal Procedure, *Texts for Bioethics* (Athens-Komotene, Edition Ant. N. Sakkoulas, 2002) p. 460. In original language: Εθνική Επιτροπή Βιοηθικής, Απόφαση για την Χρήση Γενετικών Αποτυπωμάτων στην Ποινική Διαδικασία, *Κείμενα για την Βιοηθική* (Αθήνα-Κομοτηνή, Εκδόσεις Αντ. Ν. Σάκκουλα, 2002) σ. 460.


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