'Big data analytics' and processing of health data for scientific research purposes : Cyprus’s legal framework

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1. Overview of the legal framework

First, we would like to get an overview of the current and upcoming legal framework applying to the processing of health data for research purposes in your country.

a. Which laws regulate the processing of health data for research purposes (the current regime, in force till 25 May 2018)

What are the relevant applicable provisions governing the processing of health data in your country? Please provide online references (also to an English version, if available), a brief description and any specific relevant information.

1. The Constitution of the Republic of Cyprus

[The text of the Constitution in English is available here:

http://www.presidency.gov.cy/presidency/presidency.nsf/all/1003AEDD83EED9C7C225756F0023C6AD/$file/CY_Constitution.pdf]

The Right of Privacy is safeguarded by Article 15(1) of the Constitution which reads:

1. *Every person has the right to respect for his private and family life.*

2. *There shall be no interference with the exercise of this right except such as is in accordance with the law and is necessary only in the interests of the security of the Republic or the constitutional order or the public safety or the public order or the public health or the public morals or for the protection of the rights and liberties guaranteed by this Constitution to any person.*

Article 15(1) is modelled after Article 8 of the European Convention of Human Rights, which proclaims a right to privacy as such: in turn fashioned in the spirit of the 1948 UN Universal Declaration of Human Rights. According to Cypriot jurisprudence, the right to privacy extends to inherently private, personal, and family matters objectively identifiable as such. This is always on the condition that the beneficiary of the right has not by his own action exposed the matter to public view.

2. The Processing of Personal Data (Protection of the Person) Law of 2001 as amended

[Law on the Processing of Personal Data (Protection of the Individual) of 23 November 2001, Law No. 138(I)/2001, as amended by the Processing of Personal Data (Protection of the Individual) (Amending) Law of 2 May 2003, Law No. 37(I)/2003 and the Processing of Personal Data (Protection of the Individual) (Amending) Law of 11 July 2012, Law No. 105(I)/2012 (collectively, the "Data Protection Law")

Consolidated version in Greek:

http://www.dataprotection.gov.cy/dataprotection/dataprotection.nsf/All/B708D98FB15F8D09C2256D9B0032AE61/$file/138(I)-2001&37(I)-2003&105(I)-2012_el.pdf?OpenElement

English version – not consolidated:

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Law No. 138(I)/2001:

http://www.dataprotection.gov.cy/dataprotection/dataprotection.nsf/697e70c0046f7759c2256e8c004a0a49/f8e24ef90a27f34fc2256eb4002854e7/$FILE/138(I)-2001_en.pdf

Law No. 37(I)/2003

http://www.dataprotection.gov.cy/dataprotection/dataprotection.nsf/697e70c0046f7759c2256e8c004a0a49/f8e24ef90a27f34fc2256eb4002854e7/$FILE/37(I)-2003_en.pdf]

Data protection issues in Cyprus are primarily governed by the Processing of Personal Data (Protection of the Individual) Law of 2001 (the Data Protection Law) which entered into force on November 23, 2001. The Law was amended in 2003 in order to harmonize Cypriot legislation with Directive 95/46/EC. The Law was further amended in 2012 by Law No. 105(I) of 2012. Secondary legislation in the form of Regulations has been enacted, namely, the Processing of Personal Data (Permits and Fees) Regulations of 2002, which were issued on November 8, 2002.

As with other laws that derive from the 1995 EU Data Protection Directive, the Law applies to a broad range of activities that are deemed "processing" or "processing of personal data." Generally speaking the Law is very similar to the European directive. The Law applies to processing which is wholly or partially automated, as well as to non-automated processing of personal data, which are included or will be included in a record. The Law also regulates "sensitive data" which includes medical data. Medical data are regarded as sensitive data in accordance with this Law.

In order for the Law to apply, the processing of personal data must be carried out (1) by a data controller resident in the Republic or at a place where Cyprus law is applied by virtue of public international law; or (2) by a data controller who is not resident in the Republic who, for the purpose of processing personal data, uses automated or other means existing in the Republic, unless the processing equipment was used only for the purpose of transmitting the data through the Republic. Where the data controller is not resident, he must identify in a written statement to the Commissioner a representative who is resident in the Republic, and who will act as a substitute for the controller in respect of his rights and obligations. The controller, however, is not thereby discharged from any liability. The Law does not apply to the processing of personal data which is carried out by a natural person for the exercise of exclusively personal or domestic activities.

The Law sets out the conditions which data controllers must keep in place for the permitted processing of personal data and defines what kind of processing of personal data is allowed. It also states the general principle that the collection and processing of sensitive data is prohibited, but at the same time the Law provides for a number of exceptions to this rule. It defines precisely which details the data controller must notify to the Commissioner with regard to the notification requirements concerning the operation of a record or the commencement of processing according to the Law.

The Law also sets out the right of confidentiality and the obligation to ensure security of processing. Furthermore, it states the rights of data subjects such as the right of information, the right of access to personal data which relate to them, the right to temporary judicial protection and the right to damages. Under the general heading of Sanctions, the Law sets out a number of administrative sanctions, which the Commissioner may impose on data controllers for violation of their obligations under the Law; and defines the types of offences

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3. The Law on the Protection of the Rights of Patients and Related Issues of 2005 as amended ['Patients' Rights Law']

[The Law is available in English at the following link:

http://www.olc.gov.cy/olc/olc.nsf/all/00F2DCACC3FE3EC4C225748E001D0005/$file/N.1(I)%202005.pdf?openelement]

The rights and duties of healthcare providers and patients are regulated by the Patients' Rights Law. The Law forms a comprehensive regulation of patient rights. It safeguards, inter alia, the good quality and continuous care of health; the choice of physicians and institutions; and treatment that does not violate the integrity of the person. The Law sets out certain requirements and imposes obligations upon the Health Institution or Health Care Services Provider in relation to patients' medical files, which also apply by analogy to electronic health records. It is in conformity with the Convention on Human Rights and Biomedicine of 1997 and also with the Declaration of Amsterdam of 1994.

The Law safeguards, inter alia:

(a) the good quality and continuous care of health;

(b) the choice of doctors and institutions;

(c) treatment that does not violate the integrity of the person.

It also provides for mechanisms monitoring the protection and respect of patients' rights.

4. Clinical Trials legislation

Where Clinical Trials are concerned, the Cyprus National Bioethics Committee was established under the Bioethics (Establishment and Function of the National Committee) Law of 2001.[1]

[The law is available in English:

http://www.bioethics.gov.cy/Moh/cnbc/cnbc.nsf/All/98250101CC184B0BC2257CCA003B6288?OpenDocument]

The Committee`s mission is the constant monitoring, survey, systematic analysis and evaluation of the issues and problems that relate to the scientific research, progress and implementation of the sciences of biotechnology, biology, medicine, genetics and pharmaceutics as well as to the human intervention on the biological procedure and the human genotype and the investigation of their moral, deontological, social, humanistic and legal dimensions.

The Cyprus National Bioethics Committee is the body responsible for the bioethical review of all research protocols involving human subjects in Cyprus and has established Operational Guidelines (Code of Practice in biomedical research) for the Establishment of Ethics Committees in reviewing Biomedical Research involving Human Subjects (P.I. 175/2005). These are based on the operational guidelines of the World Health Organisation (WHO) and form the basis of the operational guidelines for biomedical research involving human subjects in Cyprus and were enacted on the 31st of March 2005 by Ministerial Decree. For the purposes of these Operational Guidelines, biomedical

1 http://www.bioethics.gov.cy/Moh/cnbc/cnbc.nsf/All/98250101CC184B0BC2257CCA003B6288?OpenDocument

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research includes research on pharmaceuticals, medical devices, medical radiation and imaging, surgical procedures, medical records, and biological samples, as well as epidemiological and psychological investigations.

In accordance with the above Guidelines, the Committee formed three (3) Review Bioethics Committees: (i) The Review Bioethics Committee for 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 Beings and their biological substances and the clinical trials on Medicinal Products of Human Use.

The Review Bioethics Committees review protocols relating to biomedical research on human beings and their biological substances, clinical trials on medicinal products for human use, and, research on medical devices applied on human beings.

The Medicinal Products for Human Use (Good Clinical Practice), P.I. 452/2004 and P.I. 318/2006 are also relevant. The set out the framework for non-interventional clinical studies. It should be noted, that the non-interventional clinical studies involving medicinal products for human use, must be submitted to the Cyprus National Bioethics Committee for bioethical review which needs to verify that the provisions of the legislation are met and that there will be no intervention at all on the research participants.

5. The "Law for the Application of Patients' Rights in Cross- border Healthcare of 2013 (Law No. 149(I)/2013) (hereinafter referred to as "Cross-Border Healthcare Law").

The Cross Border Health Care Law stipulates that the Ministry of Health as the Responsible Authority has to ensure that patients from other Member States of the E.U. who receive treatment in Cyprus and vice versa have the right to access to at least one copy of their medical file, either medical or paper based, as specified in the Data Protection Law and that they have a right to a summary of their treatment either in paper or electronically for the purpose of continuation of their treatment in other Member States.[2]

6. Medical Institutions and Services (Regulation and Fees) Law of 1978 (40/1978) to 2015 and the

Government Medical Institutions and Services (General) Regulations of 2000 to 2017

[The Law is available in Greek here: http://www.cylaw.org/nomoi/indexes/1978_1_40.html]

[The Regulations are available in English here:

https://www.moh.gov.cy/moh/moh.nsf/A8834545F9596428C2257BAD00457482/$file/%CE%9F%CE%99_%CE%A0%CE%95%CE%A1%CE%99_%CE%9A%CE%A5%CE%92%CE%95%CE%A1%CE%9D%CE%97%CE%A4%CE%99%CE%9A%CE%A9%CE%9D_%CE%99%CE%91%CE%A4%CE%A1%CE%99%CE%9A%CE%A9%CE%9D_%CE%99%CE%94%CE%A1%CE%A5%CE%9C%CE%91%CE%A4%CE%A9%CE%9D_%CE%9A%CE%91%CE%99_%CE%A5%CE%A0%CE%97%CE%A1%CE%95%CE%A3%CE%99%CE%A9%CE%9D_%CE%93%CE%95%CE%9D%CE%99%CE%9A%CE%9F%CE%99_%CE%9A%CE%91%CE%9D%CE%9F%CE%9D%CE%99%CE%A3%CE%9C%CE%9F%CE%99.pdf]

[2] https://www.moh.gov.cy/moh/cbh/cbh.nsf/index_en/index_en?OpenDocument

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Patients' rights are also regulated by the Government Medical Institutions and Services (General) Regulations which were adopted on the basis of the Medical Institutions and Services (Regulation and Fees) Law. On the basis of these Regulations, and for the purpose of providing guidance as to their application, the Ministry of Health has also prepared a Booklet called "Charter of Patients' Rights during Hospitalisation at National Medical Centres", published in April 2008.

[The Charter of Patients' Rights is available here:

http://www.moh.gov.cy/moh/moh.nsf/All/943304EADC5C05D1C2257428001BF326/$file/Karta%20Nosilias-Dikaiom.%20politi.pdf?OpenElement

7. The National Health System Law of 2001 (the NHS Law)

[Law 89(I) of 2001 as amended by Laws No. 134(I) of 2002, 101(I) of 2004, 62(I) of 2005 and 74(I) of 2017

The up to date consolidated Law is available in Greek here: http://www.cylaw.org/nomoi/enop/non-ind/2001_1_89/index.html

The 2001 version of the Law in English is available here:

http://www.hio.org.cy/docs/nomos%20gesy%20english.pdf]

On 20 April 2001, the House of Representatives enacted the National Health System Law of 2001, Law 89(I) of 2001 (the 'NHS Law') which provides for free health care at the time of delivery for the whole population, to be financed by contributions from the state, employers, the self-employed, pensioners and all those who have non-employment incomes. This Law was amended in 2004 to for the purposes of harmonisation with Council Regulation no. 1408/71/EC and was later amended in June 2017 for the purposes of harmonization with Directive 89/105/EEC relating to the transparency of measures regulating the prices of medicinal products for human use and their inclusion in the scope of national health insurance systems.

The Law as amended in 2017 provides for the right of patients, once the system is implemented, to choose the services of a personal physician in the public or private sector. Personal physicians will have an obligation to maintain lists of beneficiaries to whom they provide healthcare services.

The Law also introduces provisions on the "IT System", namely an IT system developed and operated by the Organisation established under the Law. Healthcare providers have an obligation to use this IT system for issuing referrals and prescriptions, request payments, manage the list of beneficiaries and carry out any other functions that will be prescribed by the Organisation. Users of the IT system are required to comply with the security measures to be laid out in the terms and conditions of use of the IT system and in accordance with the Data Protection Law. Beneficiaries of the system will also be entitled to use the system. (Section 32C of the NHS Law)

8. Private Health Institutes (Control, Establishment and Operation) Law of 2001 as amended

[http://www.cylaw.org/nomoi/indexes/2001_1_90.html]

The Law concerns the licensing procedures for private hospitals and clinics. It contains a provision on the prohibition to reveal any information which constitutes a criminal offence in case of breach (section 24 of the Law). More specifically, no person can reveal any information obtained by means of the application of this Law. Furthermore, the Law contains various provisions on the books and records that need to be kept by private hospitals/clinics (Part XI of Annex I).

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9. The Statistics Law of 2000 (15(I)/2000)

[The Greek text of the Law is available here:

http://www.cylaw.org/nomoi/enop/non-ind/2000_1_15/index.html

The English text is available here:

http://www.mof.gov.cy/mof/cystat/statistics.nsf/All/E2AB7488CA1C7FDDC2256C6F005374A7/$file/Statistics%20Law%202000.pdf?OpenElement]

The Statistics Law forms the legal basis for the collection, production and dissemination of statistical information and includes general provisions governing the statistical system in Cyprus. It also specifies the tasks of the Statistical Service and defines its role and function as the agency responsible for the production of official statistics. The Statistical Service of Cyprus (CYSTAT) is the competent authority responsible for the compilation and the publication of most of the official statistical data in Cyprus. CYSTAT is mainly concerned with the initiation, organisation and carrying out of various censuses, surveys and statistical enquiries of an economic, demographic, social or environmental content and the publication of the results.

Among the issues included in the new legislation are provisions for the setting up of a Statistical Advisory Council, the preparation of five-year and annual work programmes, the access to administrative records and the technical autonomy, the rules of confidentiality as well as the use of common classifications and practices by all actors in the statistical system. In addition, the Statistics Law provides for the carrying out of statistical enquiries decided upon by the EU and the transmission of data subject to statistical confidentiality to Eurostat.

Where health data are concerned, CYSTAT has recently published in 2018 an annual report "Health and Hospital Statistics"[3] for the year 2016. The Report provides statistical information mainly referring to the medical services of the public sector, as well as few information of the private sector. It provides, inter alia, data on in-patients, surgical operations, out-patient attendances, bed-occupancy rates, information on medical, nursing and paramedical personnel, various health indicators etc.

b. Revision of the current legal framework under the GDPR

How are the necessary changes to the national data protection framework introduced by the GDPR addressed in your country? What is the adopted legislative approach?

For the purpose of complying with the General Data Protection Regulation, a Bill of Law was published on the 4th of April 2018 on the website of the Data Protection Commissioner for public consultation. The Bill of Law is entitled "*Protection of individuals with regard to the processing of personal data and on the free movement of such data Law of 2018*" and was prepared for the purposes of the effective implementation of certain provisions of the General

[3] Date of Release: March 2018.

http://www.mof.gov.cy/mof/cystat/statistics.nsf/All/39FF8C6C587B26A6C22579EC002D5471/$file/HEALTH_HOSPITAL_STATS-2016-EN-300318.pdf?OpenElement

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Data Protection Regulation.[4] The Bill of Law was prepared by the Data Protection Commissioner's Office, following comments from the Ministry of Justice and Public Order and the Legal Service.

The Bill of Law will be adopted by the House of Representatives before the 25th of May 2018. The Bill of Law includes provisions for the implementation of certain Articles of the General Data Protection Regulation and provides for the repeal of the existing Law on the protection of personal data.

The Data Protection Commissioner's Office and the Legal Service are still in the process of finalizing the Bill of Law. Within the context of the public consultation, interested persons and organizations could send comments to the Data Protection Commissioner's Office until the 27th of April 2018.

c. The national data processing authority

Can you provide a short description of the role of the data protection supervisory authority in your country in the domain of processing health data for research purposes under the current legal framework?

1. Commissioner for the Protection of Personal Data

The Data Protection Law appoints the Commissioner for the Protection of Personal Data (otherwise referred to as the Data Protection Commissioner) as the principal regulatory body. Pursuant to section 18, the Commissioner is responsible for ensuring the application of the Law and Regulations concerning the protection of individuals from the processing of personal data.

The Commissioner is appointed by the Council of Ministers following the recommendation of the Minister of the Interior and after consultation with the House Committee of European Affairs. The Commissioner must be a person who holds or held in the past the qualifications for appointment as judge of the Supreme Court of Justice. The Commissioner cannot be discharged during the term of her service except for reasons of mental or physical disability or incapacity rendering her incapable to fulfil his duties. As soon as the Council of Ministers ascertains the existence of one of these facts, it publishes a notification in the Official Gazette of the Republic that from a specific date she will no longer hold the position. The Commissioner holds office for a term of four years, which may be renewed for one more term.

Section 22 of the Law establishes the Office of the Commissioner to assist the Commissioner in the exercise of her duties. It consists of officers having such qualifications and serving under such terms as are set out in regulations. The Commissioner may authorise any officer to exercise any of her powers on her behalf.

The Commissioner has a number of powers as set out in Section 23 of the Law, namely:

4 http://www.dataprotection.gov.cy/dataprotection/dataprotection.nsf/page3a_gr/page3a_gr?opendocument

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(a) Issuing directions concerning the unified application for the regulation of the protection of the individual from the processing of personal data;

(b) Inviting and assisting professional associations and other unions of natural or legal persons who maintain records of personal data in setting up of codes of ethics for the more effective protection of private life and the inherent rights and fundamental freedoms of natural persons in the field of their activities;

(c) Directing and publishing recommendations and suggestions to data controllers;

(d) Issuing permits under the Law;

(e) Reporting violations of the Law to the competent authorities;

(f) Imposing administrative sanctions;

(g) Assigning to officers of his Office the carrying out of administrative research;

(h) Making administrative checks of any data record, whether on her own accord or following a report. For this purpose, she has the right to access personal data and collect any kind of information, without being restricted by any form of confidentiality obligation, except that of legal privilege. However, the Commissioner does not have access to the identity details of his colleagues who are mentioned in records kept for the purposes of national security or for the investigation of particularly serious crimes. The Commissioner examines in person records kept for purposes of national security;

(i) Deciding upon any matter concerning the regulation of the protection of personal data;

(j) Issuing rules, directions and taking actions for the regulation of special, technical and detailed matters under the Law;

(k) Compiling a yearly report on the carrying out of her duties during the previous calendar year. In the report, she indicates any desirable legislative amendments for the protection of individual from the processing of personal data. The report is submitted by the Commissioner to the Minister of the Interior who ensures its publication;

(l) Investigating complaints relevant to the application of the Law and the protection of the rights of the applicants when these concern the processing of personal data which relate to them. She also investigates applications seeking to monitor and ascertain the legality of processing and informs the applicants of her actions;

(m) Keeping all Registries provided for under the Law; and

(n) Co-operating with the respective Authorities of other Member States of the European Union and of the Council of Europe on issues relevant to the exercise of her functions.

2. <u>The Health Insurance Organisation</u>

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According to the NHS Law, the Health Insurance Organisation established under the NHS Law, which is in charge for the development and operation of an "IT System" for health services, is in charge of securing the compliance of users of the IT system with the security measures to be laid out in the terms and conditions of use of the IT system and in accordance with the Data Protection Law. It is presumed that Health Insurance Organisation and the Data Protection Commissioner will have concurrent powers on data protection issues in view of the fact that the law specifically stipulates that the provisions of the Data Protection Law apply.

3. Ministry of Health

The Patients' Rights Law confers supervisory powers to the Ministry of Health as the competent authority in respect of this law. Nevertheless, where medical records are concerned, section 18 provides that the patient shall have the right to be informed of, to have access to and to object to, data relating to him, which is contained in the medical records and, in the exercise of these rights, the provisions of sections 11 to 14 of the Processing of Personal Data (Protection of Individuals) Law of 2001 as amended shall apply, mutatis mutandis. As a consequence, the Data Protection Commissioner has concurrent powers for the safeguarding of patients' rights.

4. The Statistical Service

According to the Statistics Law (section 10), in the exercise of its functions by virtue of this Law, the Statistical Service (CYSTAT) has the right of free access to the administrative records of the ministries and services of the government of the Republic and of public corporations, to the extent to which the data to be collected are necessary for the production of statistics. In addition, ministries, services of the government of the Republic and public corporations have the obligation to provide to the Statistical Service any information or material which is necessary for or which will be used in the production of statistics. The data collected by the Statistical Service from the sources mentioned above shall be used exclusively for the production of statistics concerning economic, demographic, social or environmental matters.

Can you describe the adopted or proposed changes to this role of the national data protection authority to ensure compliance with the GDPR?

The Draft Bill of Law that was prepared for the purposes of compliance with the GDPR provides that the Data Protection Law of 2001 as amended will be repealed although the appointment of the current Data Protection Commissioner will be valid until the end of her term of office and all acts issued by the Commissioner pursuant to the existing Data Protection Law will be valid until they are replaced.

According to section 17 of the Bill, the Data Protection Commissioner will have the responsibility of monitoring the application of the GDPR and of the new Law to be adopted as well as other rules relating to the processing of personal data. In other words, the Commissioner has a wider role as its competence will now include the responsibility of monitoring the application of the GDPR in the Republic of Cyprus, and not only of the Law. This wider scope of power is also provided in section 21 of the Bill which provides that the Data Protection Commissioner is competent to perform the duties and to exercise the powers conferred on it by the GDPR and the new Law that will be adopted, as well as the duties and powers conferred to her from time to time by any other law. Another change in the role of the Data Protection Commissioner concerns cross-border processing, where the Data Protection Commissioner shall consult the lead supervisory authority and the concerned supervisory authorities. Furthermore, according to section 22 of the Bill, an additional change is that the Commissioner may prepare and publish the list of processing operations and or cases requiring the appointment of a Data Protection Officer and may the list of controllers and

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processors to designate a data protection officer. Finally, a list of additional powers is set out in section 23 of the Bill subject to the provisions of Article 58 of the GDPR, including the power to:

(a) require the Cyprus Organisation for the Promotion of Quality to revoke an accreditation of a certification body when the Commissioner finds that the conditions for accreditation are not, or are no longer, met or where actions taken by a certification body infringe the provisions of the GDPR and the new Law to be adopted;

(b) impose restrictions on the transmission of special categories of personal data

(c) make recommendations to the government on the conclusion of agreements with other countries and conclude, draw up and sign Memoranda of Understanding

(d) inform the Attorney-General of the Republic and the Police of the infringement of the GDPR or of the Law which may constitute a criminal offence.

2. Transposition of Article 8.4 of Directive 95/46

Did your national legislator insert any additional exemptions for the processing of health data for research purposes? How is it/are they formulated? Please explain. Are there additional exemptions issued by the DPA?

Art. 8.4 of Directive 95/46: "4. Subject to the provision of suitable safeguards, Member States may, for reasons of substantial public interest, lay down exemptions in addition to those laid down in paragraph 2 either by national law or by decision of the supervisory authority."

a. Transposition of Article 8.4 of Directive 95/46

The Data Protection Law requires that where personal data is collected and processed by the data controller, such data must be accurate and, if necessary, kept up to date (section 4). Furthermore, data must be kept in a form that permits the identification of data subjects only for the period of time necessary for the fulfilment of the purpose for which the data is collected and processed. After the expiry of this period, the Data Protection Commissioner may, by a reasoned decision, allow the preservation of personal data for *historical, scientific, or statistical purposes*, if the Commissioner considers that in each specific case, the data subjects' rights or the rights of third parties are not affected.

Where sensitive data is concerned, the Data Protection Law defines "sensitive data"' as data concerning racial or ethnic origin, political opinions, religious or philosophical beliefs, participation in a union, club or trade union organisation, health, sexual life and sexual orientation, as well as anything relevant to criminal prosecutions or sentencing.

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Section 6(1) of the Data Protection Law concerns the processing of sensitive data and contains a general prohibition to the effect that the collection and processing of sensitive data is prohibited. Nevertheless, according to section 6(2), notwithstanding the provisions of subsection 6(1), the collection and processing of sensitive data, is permitted, when certain conditions are fulfilled, inter alia, where the processing is performed solely for statistical, research, scientific and historical purposes, on condition that all the necessary measures are taken for the protection of the data subjects.

In general all the conditions for exemption are the following:

(a) the data subject has given his 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;

(b) processing is necessary so that the controller may fulfil his obligations or carry out his duties in the field of employment law;

(c) 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;

(d) processing is carried out by a foundation, association or other non-profit-making organisation which has political, philosophical, religious or trade union aims, and relates solely to its members and such other persons with whom the said association, foundation or organisation retains relations by reason of its purposes. Such data may be communicated to third parties only if the data subject gives his consent;

(e) 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, (f) 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;

(f) 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;

(g) processing is performed solely for statistical, research, scientific and historical purposes, on condition that all the necessary measures are taken for the protection of the data subjects;

(h) processing is performed solely for journalistic purposes or in the framework of artistic expression and as long as the right to privacy and family life is not violated

Further to the above, medical data is regarded as sensitive data and as a result, the processing of medical data is prohibited except where the processing is executed by a person who is professionally engaged in the provision of health services. Such a person must be under a duty of confidentiality or subject to relevant codes of ethics under the condition that the processing is necessary for medical prevention, diagnosis, treatment or the administration of health services. Processing carried out exclusively for statistical, research, scientific and historical purposes is also permitted, provided that all the necessary measures for the protection of the data subjects are taken.

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Section 11 of the Data Protection Law concerns the right of the data subject to be informed and imposes certain obligations on the data controller to provide the data subject with various information at the time of collection of the personal data from the data subject. Subsection (3)(b) however contains an exemption from this obligation and provides that, where the data are collected from third parties or where it is anticipated that they will be communicated to third parties, there is no obligation to inform in cases where the processing is performed *for statistical and historical purposes* or for purposes of *scientific research* if it is impossible to inform the data subject or where disproportionate effort is necessary in order to inform him, or if the communication of data is provided by another law, provided that in each case a license is issued by the Commissioner

b. The regime applying to the processing of personal data for health research purposes

Is there a specific regime applying to data processing for research in the field of health purposes?

The applicable legal regime in Cyprus regarding data collected for *research and statistical purposes* is very general. According to section 6 of the Data Protection Law, processing carried out exclusively for *statistical, research, scientific and historical purposes* is permitted, provided that all the necessary measures for the protection of the data subjects are taken. The terms "historical", "statistical" and "scientific" are not further defined in the Data Protection Law.

The legal situation can be summarised as follows: 1) comprehensive information should be given to the data subject, 2) the person concerned should have given his/her explicit consent to process the data, and 3) an exemption is possible only under specific conditions.

Where the Statistics Law is concerned, section 2 of the law defines «*statistical data*» or «*data»* as every piece of information that may be collected and presented in statistical form. The term *«statistics»* is also interpreted as quantitative, classified and representative data, resulting from the collection and systematic processing of the data. *«Production of statistics»* is interpreted as the whole range of the activities required for the collection, storage, processing, compilation, analysis and dissemination of statistical data. Finally, the term «*survey»* is further interpreted as (a) a census; (b) the systematic or ad hoc *sampling survey*, of a general or limited nature, conducted for the purpose of production of statistical data in relation to *economic, demographic, social or environmental matters*. The subjects of the survey are referred to as «statistical units» which is defined as natural or legal persons, households, premises, enterprises, agricultural or other holdings and any unit or entity which may constitute the subject of a survey

In the exercise of its functions by virtue of the Statistics Law, the Statistical Service has authority to require from any person the provision of data for the purposes of a survey or work which is being carried out by virtue of this Law. The Statistical Service also has the right of free access to the administrative records of the ministries and services of the government of the Republic and of public corporations, to the extent to which the data to be collected are necessary for the production of statistics. In addition, the ministries, the services of the government of the Republic and the public corporations have the obligation to provide to the Statistical Service any information or material which is necessary for or which will be used in the production of statistics. (Section 10 of the Statistics Law). The

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Statistical Service may assign the conduct of any survey or part of a survey or work relating to a survey, to the private sector, on a public contract. (Section 8 of the Statistics Law).

In addition, the Statistics Law provides for the carrying out of statistical enquiries decided upon by the EU and the transmission of data subject to statistical confidentiality to Eurostat. The Statistics Law contains certain provisions on statistical data that may be collected and presented in statistical form and safeguards statistical confidentiality of data collected and processed by the Statistical Service.

The areas in which the Statistical Service can produce statistics and carry out censuses concern *economic, demographic, social or environmental matters*. According to the Dissemination and Pricing Policy of the Statistical Service of Cyprus,[5] the various statistical data are categorized in the web pages under 10 "Statistical Themes" and 29 subthemes. The "Statistical Themes" are: - *Economy, Industry / Construction, Population and Social Conditions, Services, Labour, Energy / Environment, External Trade, Science and Technology, Agriculture, General*.

The Statistical Service compiles a five-year programme of statistical activities, which includes the surveys or work which will be carried out during this period. The five-year programme refers to the purpose of every survey or work and gives a general description thereof. The five-year programme of statistical activities must first be approved by the Council of Ministers. The Statistical Service also prepares an annual programme of statistical activities which includes the surveys or the work referred to in the five-year programme which will be carried out during the year under reference. The five-year and the annual programmes of statistical activities are compiled prior to the commencement of the period to which they relate by the end of May of every fifth year and of each year respectively. Furthermore, in case the Council of the European Union or the Council of the European Union and the European Parliament decide on the conduct of a survey on the basis of section 3(2) (a) of the Regulation of the Council with number 322/97 and date 17th February 1997, the said survey shall be incorporated in the five-year programme of statistical activities without any further procedure. In addition, in case a survey is conducted on the basis of an agreement between the competent national authorities and the Statistical Office of the European Communities (Eurostat), the said survey shall be incorporated in the five-year programme of statistical activities (section 15 of the Statistics Law).

It can be extracted that the Statistics Service has competence to collect data for any matters including *medical and health* related matters as they relate to the above objectives. To this effect, CYSTAT collects statistical data on an annual basis regarding health and hospitals.

The most recent report was published in 2018 entitled "Health and Hospital Statistics"[6] for the year 2016. The Report provides statistical information mainly referring to the medical services of the public sector, as well as few information of the private sector. Its aim is to provide basic information with regard to medical services offered by the public sector and a comprehensive picture of the general level of health and morbidity in Cyprus. The data presented refer to in-patients treated and discharged from the general and rural hospitals, surgical operations

[5] http://www.mof.gov.cy/mof/cystat/statistics.nsf/dissemination_en/dissemination_en?OpenDocument

[6] Date of Release: March 2018.

http://www.mof.gov.cy/mof/cystat/statistics.nsf/populationcondition_23main_en/populationcondition_23main_en?OpenForm&sub=3&sel=4

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performed on in-patients and out-patients, out-patient attendances at the general hospitals, special hospitals, rural hospitals and health centres, bed occupancy rates, paramedical services, various health indicators, expenditure on health services, causes of death and health personnel. The analysis by diagnosis on data for 2016 was based on in-patient cases (discharges) reported to the Statistical Service of Cyprus from the IT unit of the Ministry of Health. Due to lack of detailed data for the private sector, the data presented mainly refer to the public health services only. The only data available for the private sector refer to the number of doctors, dentists, nurses, clinics, beds, as well as the number of discharges, bed days, etc.

The Patients' Rights Law contains specific provisions on the participation of patients in scientific research or experimental treatment (section 14(1)). The participation of a patient in scientific research or experimental treatment shall be allowed only in the following circumstances:

(a) there is no alternative solution of comparable effectiveness;

(b) the risks which may be incurred by that patient are not disproportionate to the potential benefits of the research;

(c) the research project has been approved by the competent body after independent examination of its scientific merit, including assessment of the importance of the aim of the research and multi-disciplinary review of its ethical acceptability;

(d) the patient has been informed of his rights prescribed by this Law;

(e) the necessary written consent of the patient provided for under section 13, has been given specifically and in writing after a complete medical information

According to section 14(2), where the patient is not able to consent, research may be undertaken only if the following conditions are met:

(a) the conditions mentioned in paragraphs (a) to (d) of subsection (1) of section 14(1) are met;

(b) the results of the research have the potential to produce real and direct benefit to his health;

(c) research of comparable efficiency cannot be carried out on individuals capable of giving consent;

(d) the necessary authorization provided for in section 13 of the Law has been given specifically and in writing; and

(e) the person concerned does not object.

Furthermore, according to section 15 of the Patients' Rights Law under certain conditions the medical institution or the competent health care services provider may disclose medical information to a third party. According to section 15 (2) this is possible, if:

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(a) the patient has given his/her written consent. The patient's consent may be presumed, where disclosure is to a person involved in the patient's treatment;

(b) the disclosure is for the purpose of the patient's treatment by another health care service provider;

(c) the information is disclosed to the medical institution providing health care to the patient or to a member of its staff for the purposes of processing, or filing the information, or for notification required by law;

(d) the disclosure of information is *for the purpose of publication in medical journals or for research or teaching purposes, provided that all information identifying the patient is not disclosed;*

(e) there is a legal obligation to this effect;

(f) the Board of the Pancyprian Medical Association has decided, after giving both the medical practitioner and the patient an opportunity to express their views, that the non-disclosure of the information could possibly cause serious harm to other persons´ health or physical integrity or have serious impact to the society as a whole.

When information is being disclosed to the extent that the case requires, every effort shall be made to keep the identity of the patient secret.

From which generally applicable data protection provisions are researchers exempted and under what conditions?

The Data Protection Law (section 4) generally provides that data must be kept in a form that permits the identification of data subjects only for the period of time necessary for the fulfilment of the purpose for which the data is collected and processed. After the expiry of this period, the Data Protection Commissioner may, by a reasoned decision, allow the preservation of personal data for *historical, scientific, or statistical purposes*, if the Commissioner considers that in each specific case, the data subjects' rights or the rights of third parties are not affected.

Furthermore, the collection and processing of sensitive data, is permitted, when certain conditions are fulfilled, inter alia, where the processing is performed solely for statistical, research, scientific and historical purposes, on condition that all the necessary measures are taken for the protection of the data subjects.

In addition, according to the Statistics Law and the Code of Practice for the Collection, Publication and Storage of Statistical Data researches are entitled to collect and process data provided that they safeguard statistical confidentiality at the stage of publication of statistical Data.

According to sections 14 and 15 of the Patients' Rights Law researchers may obtain and disclose health data of patients without consent where:

(a) the research project has been approved by the competent body after independent examination of its scientific merit, including assessment of the importance of the aim of the research and multi-disciplinary review of its ethical acceptability

(b) for the purpose of publication in medical journals or for research or teaching purposes, provided that all information identifying the patient is not disclosed. For this purpose, every effort shall be made to keep the identity of the patient secret.

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(c) All information and data that may possibly reveal the identity of the patient should be protected

c. Are there additional specific conditions governing the processing of data for scientific research purposes?

What are the suitable safeguards applied to the exemption foreseen by Article 8.4 of the Directive in your country?

The text of Article 8 (4) of the Directive requires that the processing of sensitive data, when authorised by the Member States for reasons of significant public interest, are subject to ***suitable safeguards***. According to the Data protection Law (section 4), the preservation of personal data for historical, scientific, or statistical purposes may be permitted if the *data subjects' rights or the rights of third parties are not affected*.

According to section 14 of the Patients' Rights Law, an independent examination of its scientific merit, including assessment of the importance of the aim of the research and multi-disciplinary review of its ethical acceptability must be carried out. Furthermore, where medical data is disclosed by a medical institution to a researcher, all information and data that may possibly reveal the identity of the patient should be protected and every effort to keep the identity of the patient must be made.

Are there any specific provisions concerning: (i) professional secrecy, (ii) express consent for specific data, or specific provisions for (iii) deceased data subjects, or (iv) specific provisions for minors or persons subject to guardianship?

Secrecy and confidentiality

It should also be noted that according to the Statistics Law, the Statistical Service is governed by the principles of suitability, impartiality, reliability, transparency and statistical confidentiality. Where statistical confidentiality is concerned, section 13(1) of the Statistics Law provides the following:

(a) the data collected and processed by the Statistical Service for the production of statistics are considered to be confidential as long as they allow the direct or indirect identification of statistical units and disclose personal data. Data which have been gathered from sources which are accessible to the public are not considered as confidential.

(b) A statistical unit is identified directly by its name and address or by a registration number which has officially been granted to it.

(c) A statistical unit is identified indirectly if it is possible to ascertain its identity in a manner other than that which is provided in paragraph (b) above. In order to ascertain whether a statistical unit may be identified indirectly, all the means shall be considered which may reasonably be used for the identification of the specific statistical unit.

Section 13(2) provides that it is possible to have access to confidential statistical data which allow the indirect identification of statistical units following the permission of the Director, where these statistical data are necessary

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for specific scientific research programmes the results of which do not disclose specific statistical units and will not be used for commercial purposes.

Section 13(3) provides that the statistics compiled on the basis of the data resulting from a survey shall be published in such a manner as to render impossible the direct or indirect disclosure of the identity of those who provided the data or of the persons to whom the data relate.

Section 13(4) provides that all the data collected during a survey or work shall continue to be considered as confidential, despite that the statistical results of the specific survey or work have been published.

According to section 13(5) any officer of the Statistical Service, any person duly authorized by it, any officer of a Ministry or service of the government of the Republic and any officer of a public corporation who has authority to require from any person the provision of data for the purposes of a survey or work which is being carried out by virtue of the Statistics Law, have the obligation to make a confirmation that they will not disclose information which they have received during the conduct of the survey. This obligation continues to exist after the termination of their professional relationship with the service for which they have collected the information. Any person who violates this obligation is guilty of an offence and in case of conviction is liable to a fine or to imprisonment or both.

The Statistical service generally collects concentrated and impersonal / generic data and makes an effort not to collect any personal details of enterprises and individuals. In the event that such personal data is collected that could identify individuals, they are kept in separate records. Namely a code number is granted to a person or enterprise. The code number is kept in one record and the actual details of the enterprise or person are kept in a separate record. One officer cannot have access to both records because the records are not linked together and they are kept separate. In addition, the statistics compiled on the basis of the data resulting from a survey are published in such a manner as to render impossible the direct and indirect disclosure of the identity of those who provided the data or of the persons to whom the data relate.

The Statistical Service has developed a Code of Practice for the Collection, Publication and Storage of Statistical Data which cites the specific actions and the precautions that have to be taken in every stage of handling statistical data, in order to safeguard statistical confidentiality. The Code is available on the website of the Statistical Service:[7]

The scope of this document is to cite the specific actions and the precautions that have to be taken in every stage of handling statistical data, in order to safeguard statistical confidentiality. In the process of collecting data, the highest responsibility, in terms of protecting confidentiality, lays with the authorised (by the Statistical Service) persons in charge of collecting data (permanent or temporary staff).

The staff ought to be adequately informed that disclosing data received, either orally or in writing, to non-authorised persons is prohibited. Special attention should be given when data is collected during a personal interview. The interview must not take place in the presence of third parties and, during the interview, questionnaires involving other statistical units should not be exposed in any way. Additionally, interviewers should not discuss about data or information obtained from another person or enterprise. It is forbidden to disclose confidential data even after the termination of employment of the person working in a specific survey and, generally, in the Statistical Service.

[7] http://www.mof.gov.cy/mof/cystat/statistics.nsf/dmlquality_en/dmlquality_en?OpenDocument

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Each interviewer or person in charge of collecting or/and processing data has to:

(a) take, in his/her own responsibility, an oath before the Registrar of any District Court within a week from the completion of his/her training.

(b) sign the confirmation envisaged by the Law concerning the observance of statistical confidentiality, and also to

(c) sign the solemn statement that he/she is advised of the Statistics Law with all its provisions and penalties.

The above mentioned sworn statement (confirmation) is necessary for all personnel (permanent and temporary) and needs to be taken only once. The solemn statements of the interviewers will be signed for every survey in which they participate at the same time with the signing of their contract. Afterwards and within 10 days, these solemn statements need to be submitted to the Registry, under the responsibility of the person in charge of the survey.

The interviewer, in every meeting with a person that will be required to provide data, has to carry with him the special identification (authorisation) card from the Statistical Service that is valid for a specific time period. If employment is terminated before the end date, then this card should be immediately returned to the Statistical Service.

All the above apply also to the staff engaged in the data entry of questionnaires and other documents.

Where the publication of statistical data is concerned, the provisions laid down in order to safeguard statistical confidentiality at this stage of handling statistical data are the following:

1. Publication of aggregated data in tables can be done with no problem when:

(a) The number of statistical units concerned is at least three.

(b) The number of statistical units is less than three and the appropriate consent of these units for publishing the data has been obtained beforehand. This consent may be sought, for example, in the cases of products of special significance and interest to the public.

(c) Cells at a lower level of disaggregation are merged in order to increase the number of statistical units in a certain stratum.

(d) The statistical units concerned are government administrations and services, semi-government organisations or public companies.

2. Publishing data at the lowest level of a classification (e.g. at the fifth-digit level of NACE) should be avoided so as to minimise the risk of a possible matching of the data with the statistical units that have provided them.

3. The Business Register may be made available to the public under certain conditions. It should not include variables such as the number of persons employed or the turnover, but only the name, the address and the economic activity of each enterprise. The register to be made available to the public should comprise only companies, official partnerships and joint ventures. Sole proprietors are not to be included.

4. The release of information that includes confidential data may be permitted for research purposes under the following conditions:

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(a) Interested parties have to fill in the special form in order to apply for the data to the Director of the Statistical Service. The application submitted needs to include the following information, which will constitute the criteria upon which a decision for releasing or not the requested data will be based:

(i) Details of the applicant: educational institution, research organisation, business enterprise, private individual, etc.

(ii) Description of the research project, use of the data requested, potential users.

(iii) Description of the data requested and justification of the need for using confidential data.

(iv) Precautionary measures taken by the applicant in order to safeguard statistical confidentiality during data processing.

(v) Description of the expected output to be published and means of its dissemination.

5. The applicant should also include a statement declaring that the data will not be used for any further purpose, will not be made available to third parties and will be disposed by destruction once the research project is completed.

The application form will be forwarded to the inter-service Confidentiality Committee, which, after examining it, will provide its recommendation to the Director by filling in the special form). The whole process, from receiving the application until the Director's decision, should not exceed one month, provided that the application received had been properly completed.

The data set that will finally be supplied according to the Director's decision should not exceed what is absolutely essential for the research project and, in any case, should not include the names of the statistical units concerned.

Information / consent of data subject

Generally, according to the Data Protection Law, the processing of sensitive data is permitted, inter alia, if the individual has given his/her explicit consent, unless such consent has been obtained illegally (section 6).

Where statistical data is concerned, the legal situation can be summarised as follows: 1) comprehensive information should be given to the data subject, 2) the person concerned should have given his/her explicit consent to process the data, and 3) only under specific conditions an exemption is possible.

Officers or the other persons of the Statistical Service collecting data under the Statistics Law have the obligation to inform the person from whom the provision of data is required about the conduct of a survey or work by virtue of the said Law, the purpose of the survey or work and statistical confidentiality. Appropriate consent of statistical units must also be obtained beforehand (section 11)

Deceased data subjects

The Data Protection law concerns living data subjects therefore its provisions would not apply. The Statistics Law does not contain any specific provisions for deceased persons. The Patients' Rights Law provides that all information about the patient's medical condition, diagnosis, prognosis and treatment, as well as any other personal data shall be kept confidential even after the death of the patient and shall not be disclosed to any person or authority (section 15).

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Minors or persons subject to guardianship

The Data Protection law contains a general provision that the collection and processing of sensitive data, is permitted, when certain conditions are fulfilled, inter alia, where the processing is performed solely for statistical, research, scientific and historical purposes, on condition that all the necessary measures are taken for the protection of the data subjects (section 6). It does not contain any specific provisions for minors. The Statistics Law does not contain any specific reference to minors either.

The Patients' Rights Law contains specific provisions for minors and other persons who do not have the physical or mental capacity to provide consent and participate in scientific research or experimental treatment. In order to participate in such project, the consent of a person appointed by law must be given. The opinion of the minor shall be taken into consideration as an increasingly determining factor in proportion to his age and degree of maturity.

Are there specific requirements about the data subject's information or about the person from whom the data was collected?

Generally, according to the Data Protection Law, the processing of sensitive data is permitted, inter alia, if the individual has given his/her explicit consent, unless such consent has been obtained illegally (section 6).

Where statistical data is concerned, the legal situation can be summarised as follows: 1) comprehensive information should be given to the data subject, 2) the person concerned should have given his/her explicit consent to process the data, and 3) only under specific conditions an exemption is possible.

Officers or the other persons of the Statistical Service collecting data under the Statistics Law have the obligation to inform the person from whom the provision of data is required about the conduct of a survey or work by virtue of the said Law, the purpose of the survey or work and statistical confidentiality. Appropriate consent of statistical units must also be obtained beforehand (section 11).

According to the Patients' Rights Law (section 12), "medical information" concerning a patient includes the following:

(a) the diagnosis of the patient's medical condition and, if possible, its prognosis;

(b) a description of the purpose, anticipated benefit and likelihood of success of the proposed treatment;

(c) the risks entailed in the proposed treatment, including side effects, pain and discomfort;

(d) the likelihood of success and the risks of various forms of treatment or non-treatment.

According to section 17 concerning the keeping of medical records, the competent health care services provider has a duty to keep medical records showing the course of the treatment of the patient. These records shall include detailed data identifying the patient and the competent health care services provider, as well as medical information on the treatment received by the patient, his previous medical record, as far as known, the diagnosis of his current medical condition and the treatment currently provided.

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Are there specific penalties if the conditions for processing for scientific research in the field of health purposes are not respected? What do those penalties entail?

The Data Protection Law provides for administrative penalties, which are a form of criminal penalties. Section 26 sets out an extensive list of offenses in relation to the processing of personal data. These offenses include, for example:

(a) Failure to notify the Commissioner of the constitution and operation of a filing system, the execution of processing or any change in the terms and conditions associated with the granting of a license or permit;

(b) Maintenance of a record without permit or in breach of the terms and conditions of a license or permit;

(c) Interconnection of records without a license or permit where this is required by the Law or in breach of the terms of a license or permit already granted;

(d) Unauthorized interference with a record of personal data, receiving knowledge of data, extracting, altering, harming, destroying, processing, transmitting, notifying, making data accessible to unauthorized persons, allowing such persons to receive knowledge of the data, or exploiting the data in any way;

(e) A data controller fails to comply with the provisions of the Data Protection Law during the processing; or

(f) The data controller transmits personal data in violation of Section 9 of the Law or does not conform to a decision of the court issued under Section 16.

Persons who have committed the above offenses and acted for the purpose of gaining an illegal benefit or harming a third party, will be liable to imprisonment of up to five years and/or a fine of up to EUR 8,543, depending on the offense.

The Commissioner may impose administrative fines on data controllers or their representatives for violation of their obligations that arise under the Data Protection Law or any other regulation that pertains to the protection of individuals with respect to the processing of personal data. These sanctions include:[37]

(a) Warning with a specific time limit for termination of the violation;

(b) Fines up to EUR 8,543;

(c) Temporary or permanent revocation of licenses or permits; or

(d) Destruction of records or suspension of processing and destruction of data.

All administrative sanctions, apart from warnings, are imposed only after a hearing of the data controller, and they are proportional to the gravity of the violation. Temporary or permanent withdrawal of permits and destruction of records or suspension of processing are imposed in particularly serious violations. Fines can be imposed

[37]Data Protection Law, Section 25(1).

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accumulatively with other sanctions. If the destruction of a record is imposed, the data controller is responsible for the destruction and a fine can be imposed on him for non-compliance. Fines are collected by the Commissioner as a civil debt.

According to the Statistics Law, the following administrative offences will be committed and the relevant penalties mentioned below will be imposed:

Refusal of data subject l to provide data for statistical purpose

Any person who refuses to provide data or who provides false, incomplete or inaccurate data is guilty of an offence and in case of conviction is liable to a fine prescribed by the Law or to imprisonment not exceeding six months or to both such fine and imprisonment (Section 11(3)).

Breach of Statistical confidentiality

Researchers have the obligation to make a confirmation that they shall not disclose information which they have received during the conduct of the survey. This obligation continues to exist after the termination of their professional relationship with the service for which they have collected the information. A researcher who violates the above obligation shall be guilty of an offence and in case of conviction is liable to a fine prescribed by the Law or to imprisonment for a term not exceeding two years or to both such fine and imprisonment (Section 13(5)(b)).

Other offences and penalties

According to section 16 of the Statistics Law, any person who voluntarily refuses or neglects to comply with or who violates any provision of the Statistics Law or the regulations made thereunder or any direction of the Director of the Statistical Service issued by virtue of the Statistics Law shall be guilty of an offence and in case of conviction is liable to imprisonment for a term not exceeding six months or to a fine prescribed by the Law or to both such imprisonment and fine.

Furthermore, any person who-

(a) participates in the conduct of a survey or work and without lawful authority makes public or communicates, beyond the ordinary exercise of his duties, to any other person any information given to him in the exercise of his duties; or

(b) while possessing information which was disclosed to him in contravention of the provisions of this Law, and while being aware of that fact, makes public or communicates the said information; or

(c) falsely makes himself out to be exercising duties by virtue of this Law or asks for information without being authorized to do so,

shall be guilty of an offence and in case of conviction is liable to imprisonment for a term not exceeding twelve months or to a fine prescribed by the Law or to both such imprisonment and fine.

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d. Formalities prior to processing: the general regime under the current framework

Is there a regime requiring the fulfilment of certain conditions prior to any processing activities different from that applicable to research in the field of health? If yes, what does that regime entail?

The registration and prior approval formalities prior to processing are set out in section 7 of the Data Protection Law. According to this section, the data controller (the person who determines the purpose and means of the processing of personal data), must notify the Data Protection Commissioner in writing about the establishment and operation of a filing system or the commencement of processing. In the notification, the controller must state:

(a) his full name, business name or title and his address. If the controller is not established in the Republic, he must state, in addition, the full name, business name or title and address of his representative in the Republic;

(b) the address where the filing system is established or the main equipment necessary for the processing is installed;

(c) a description of the purpose of the processing of the data which are or are intended to be processed or which are included or 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 intends to carry out the processing or to keep the filing system;

(g) the recipients or categories of recipients to whom he 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.

The controller is discharged from the obligation to notify, in cases where, inter alia:

(a) processing is performed solely for purposes directly connected with the work to be done and is necessary for the fulfilment of a legal obligation or for the performance of a contract provided that the data subject has been previously informed,

(b) the processing concerns customers or suppliers of the data subject provided that the data are neither transferred nor communicated to third parties.

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(c) processing is performed by doctors or other persons who provide health services and concerns 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.

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.

Furthermore, according to section 10 of the Data Protection Law, for carrying out the processing, the controller must select persons who possess appropriate qualifications and who provide sufficient guarantees as regards technical knowledge and personal integrity for the observance of confidentiality. The controller must also take the appropriate organizational and technical measures for the security of data and their protection against accidental or unlawful destruction, accidental loss, alteration, unauthorised dissemination or access and any other form of unlawful processing. Such measures shall ensure a level of security which is appropriate to the risks involved in the processing and the nature of the data processed.

Finally, according to section 24, the Commissioner keeps a Registers of Filing Systems and Processing, which includes the filing systems and processing notified to the Commissioner.

According to the Code of Practice for the Collection, Publication and Storage of Statistical Data the staff of the Statistical Service, should make sure that the procedures provided for in the IT Security Policy Handbook, developed by the Department of Information Technology Services[8], are appropriately followed so as to minimise the risk of a potential breach of data security. Particular attention should be paid in creating and storing back-up copies (either on CDs or on USBs), especially in those cases that these copies may need to be transferred out of the office. Confidential data stored in electronic form should also be kept in a safe place, either in the office of the person in charge or in the storage room

3. Further processing of health data (for research purposes): the current regime

How is the notion of further processing regulated in your national framework?

The Data Protection Law does not contain any specific definition of the term ‘further processing of personal data’. Nevertheless, the notion of ‘further processing’ could be inherent in the definition of the term "processing of personal data" which means any operation or set of operations which is performed by any person upon personal

8 http://www.mof.gov.cy/mof/dits/dits.nsf/All/A1E16919C0781BECC2257D6A002FA8A0/$file/%CE%95%CE%B3%CF%87%CE%B5%CE%B9%CF%81%CE%AF%CE%B4%CE%B9%CE%BF%20%CE%91%CF%83%CF%86%CE%AC%CE%BB%CE%B5%CE%B9%CE%B1%20%CE%A0%CE%BB%CE%B7%CF%81%CE%BF%CF%86%CE%BF%CF%81%CE%B9%CF%8E%CE%BD.pdf

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data, whether or not by automatic means, and includes not only the collection, recording, organization, preservation and storage of data but also such actions such as the alteration, extraction, use, transmission and dissemination.

Are there specific conditions to the further processing for scientific research in the field of health purposes?

According to section 4 of the Data Protection Law, the controller must ensure, inter alia, that

(a) personal data is collected for specified, explicit and legitimate purposes and are not further processed in a way incompatible with those purposes.

Provided that the further processing of data for historical, statistical or scientific purposes is not considered incompatible with the purposes for which the data were initially collected unless any action is taken with respect to a particular person.

(b) kept in a form which permits identification of data subjects for no longer than is necessary, in the 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 considers that the rights of the data subjects or third parties are not affected.

With regards to sensitive personal data (section 6 of the Data protection Law), the further processing of sensitive medical data is permitted on condition that, inter alia,

(a) It 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-

(b) processing is performed solely for statistical, research, scientific and historical purposes, on condition that all the necessary measures are taken for the protection of the data subjects

(c) processing is performed solely for journalistic purposes or in the framework of artistic expression and as long as the right to privacy and family life is not violated

At the time of collection of the data from the data subject himself, the controller must inform the data subject about the recipients or the categories of recipients and of the data. This is also the case where data is collected from third parties or where it is anticipated that the data will be communicated to third parties. nevertheless, this obligation to inform the data subject does not apply where, especially in cases where the processing is performed for statistical and historical purposes or for purposes of scientific research if it is impossible to inform the data subject or where disproportionate effort is necessary in order to inform him, or if the communication of data is provided by another law, provided that in each case a license is issued by the Commissioner (section 11 of the Data Protection Law). There is no obligation to inform where the collection is made solely for journalistic purposes.

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According to the Patients' Rights Law, section 15, provides for the ability to disclose to third parties of medical information by a medical institution or by a competent health care services provider. Such disclosure could be considered to be further processing. More specifically, a medical institution or a competent health care services provider may disclose medical information to a third person if, inter alia, the disclosure of information is for the purpose of publication in medical journals or for research or teaching purposes, provided that all information identifying the patient is not disclosed.

The Statistics Law provides (section 13) that upon the collection of data (as a result of further processing carried out on a previous stage by the controller who collected the data and disseminated it to the Statistical Service for further processing, i.e. the production of statistics), the data collected and processed by the Statistical Service for the production of statistics are considered as confidential as long as they allow the direct or indirect identification of statistical units and disclose personal data. Furthermore, the statistics compiled on the basis of the data resulting from a survey shall be published in such a manner as to render impossible the direct or indirect disclosure of the identity of those who provided the data or of the persons to whom the data relate. All the data collected during a survey or work shall continue to be considered as confidential, despite that the statistical results of the specific survey or work have been published.

The Code of Practice for the Collection, Publication and Storage of Statistical Data provides, with regards to the publication of statistical data, that the release of information that includes confidential data may be permitted for research purposes under certain conditions but such data cannot be used for any further purpose, it will not be made available to third parties and will be disposed by destruction once the research project is completed.

The provisions of the Law on Medicines for Human Use (Control, Distribution and Prices) of 2001 and of the Law establishing the National Bioethics Committee may also be relevant. All clinical trials are authorized to begin only upon approval by the National Bioethics Committee and the National Health Authority (Drugs Council). The consent of the patient must be obtained by means of a Consent Form for Participation in a Research Study.

The term clinical trial is described in section 2 of the Law on Medicines for Human Use (Control, Distribution and Prices) of 2001 as amended which provides that a clinical trial is any investigation in human subjects intended to discover or verify the clinical, pharmacological and/or other pharmacodynamic effects of one or more investigational pharmaceutical product(s), and/or to identify any adverse reactions to one or more investigational pharmaceutical product(s) and/or to study absorption, distribution, metabolism and excretion of one or more investigational pharmaceutical product(s) with the object of ascertaining its (their) safety and/or efficacy, including clinical trials carried out in only one centre or in many centres at the same time, in the Republic and/or in one or more member states [of the European Union].

The Bioethics Committee is responsible for supervising the conduct of clinical trials. In particular, the Ethics Committee is responsible for protecting the rights, safety and wellbeing of human subjects involved in a trial and to provide public assurance of that protection, by, among other things, expressing an opinion on the trial protocol, the suitability of the investigators and the adequacy of facilities, and on the methods and documents to be used to inform trial subjects and obtain their informed consent.

As for the procedure to be followed, it is as follows

Application Stage

Step 1: Submission of application to the Drugs Council for approval of clinical trial

Step 2: Submission of request to the National Bioethics Committee for its opinion

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Step 3: The Bioethics Committee issues its reasoned decision within 60 days from receiving the application for opinion and notifies same to the applicant and to the Drugs Council. The committee may request for additional information (only once) in which case the time limit is suspended until the documents are received. The time limit may also be extended for 30 days where the opinion concerns genetically modified organisms. Finally, the time limit may be extended for an additional 90 days where the National Bioethics Committee consults with other bioethics committees or subcommittees.

Commencement of clinical trial

(a) A clinical trial may be initiated only if the Ethics Committee is positive and comes to the conclusion that the anticipated therapeutic and public health benefits justify the risks. In addition, there is a requirement that the Drugs Council does not make any reasoned objections

(b) Reasoned Objections of Drugs Council: where the Drugs Council notifies any reasoned objections to the sponsor, the sponsor must amend the contents of his application, otherwise the application will be rejected and the clinical trial my not commence

(c) Time limit: The Drugs Council carries out the procedure for the approval of the application for clinical trial within 60 days from receiving the application. The time limit may be extended for another 30 to 90 days

(d) Pre-approval of certain products: For certain products, i.e. investigational pharmaceutical products not having a marketing authorization and other products, the Drugs Council may require that it issues a written pre-approval prior to the conduct of a clinical trial.

End of Clinical Trial

Within 90 days of the end of a clinical trial the sponsor must notify the Drugs Council and the National Bioethics Committee that the clinical trial has ended. If the trial has to be terminated early, this period shall be reduced to 15 days and the reasons clearly explained.

What are the rights of the data subject when it comes to further processing?

Consent of data subject

Generally, the data subject must first consent to the processing of his personal data. Section 5 of the Data Protection Law provides the right to a data subject to give his unambiguous consent in order for the processing of his personal data to be lawful, with the exception, inter alia, that processing is necessary for compliance with a legal obligation to which the controller is subject (i.e. obligation of controller to provide data to the Statistical Service upon request. For sensitive data, no consent is required where the processing is carried out for statistical, research, scientific and historical purposes according to the decision of the Commissioner and provided that all necessary measures are taken to protect data subjects (section 6).

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Furthermore, according to section 9 of the Data Protection Law, the data subject must give his consent to the transmission of his personal data outside the EU and on condition that the Commissioner grants a transmission license.

According to the Patients' Rights Law, section 15, the medical institution or the competent health care services provider may disclose medical information to a third person if the patient has given his written consent. However, no consent is required where the disclosure of information is for the purpose of publication in medical journals or for research or teaching purposes, provided that all information identifying the patient is not disclosed or where there is a legal obligation to this effect (i.e. Statistical Service requires such information on the basis of the Statistics Law).

Right to privacy and confidentiality

Generally, the Patients' Rights Law, section 16, protects the right to privacy of patients and provides that there can be no intrusion into a patient's private and family life (which is also a Constitutional right), unless with the patient's consent and if this is deemed necessary for his diagnosis, treatment or care. Furthermore, this section provides that health care shall only be provided with appropriate respect for the patient's private life and shall, as a rule, be given in the presence only of those persons who are necessary for the provision of health care.

Right of information of data subject

In general, section 11 of the Data Protection Law provides a right of the data subject to be informed at the time of collection of his personal data, of the identity of the controller and the purpose of the processing. Where further processing is concerned, the controller must also inform the data subject of the recipients or the categories of recipients and of the data (i.e. further processing) and the existence of the right of access to and rectification of the data. The above also applies where the data are collected from third parties or where it is anticipated that they will be communicated to third parties, and the data subject shall be informed during their recording or at their first communication, as the case may be.

Nevertheless, the above obligations do not apply, especially in cases where the processing is performed for statistical and historical purposes or for purposes of scientific research if it is impossible to inform the data subject or where disproportionate effort is necessary in order to inform him, or if the communication of data is provided by another law, provided that in each case a license is issued by the Commissioner.

Right of access

Section 12 of the Data Protection Law provides for the right of a data subject to know whether the personal data relating to him are or were processed. To this end, the controller must reply to him in writing and provide a copy of the personal data upon request unless a disproportionate effort is needed to do this. The data subject also has the right to ask for and receive from the controller without excessive delay and expense information about:

(a) all the personal data relating to him which have undergone processing, as well as any available information as to their source;

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(b) 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;

(c) the progress of the processing since his previous briefing;

(d) the logic which every automated process of data in relation to the data subject, is based.

The data subject also has the right to ask for and receive

(a) rectification, erasure or blocking of the data, the processing of which has not been performed in accordance with the provisions of this Law, especially due to inaccuracies or shortages.

(b) notification to third parties, to whom the data have been communicated, of every rectification, erasure or blocking, unless this is impossible or it requires disproportionate efforts.

If the controller does not reply within four weeks from the submission of the application or if his reply is not satisfactory, the data subject has the right to appeal to the Commissioner.

Right to object.

Pursuant to section 13 of the Data Protection Law, the data subject has the right to object, at any time, on compelling legitimate grounds relating to his particular situation, to the processing of data relating to him. The objection shall be in writing and addressed to the controller, and must contain a request for specific action to be taken, such as rectification, temporary abstention from use, blocking, and abstention from transmission or erasure. The controller must reply in writing on these objections within fifteen days from the submission of the request. In his reply, he must inform the data subject about the actions he has taken or the reasons for not satisfying the request, as the case may be. In case of rejection of the objections, the reply must also be communicated to the Commissioner.

If the controller does not reply within the specified time-limit or if his reply is not satisfactory, the data subject has the right to apply to the Commissioner and request that his objections be examined. If the Commissioner considers that the objections may be reasonable and that there is a risk of serious harm to the data subject as a result of the continuation of the processing, he may order the immediate suspension of the processing until he takes a final decision on the objections.

Right of temporary judicial protection.

According to section 16 of the Data Protection Law, every person has the right to apply to the competent court for the immediate suspension or non-performance of an act or decision affecting him, which has been done or made by an administrative authority or a public or private corporate body, a union of persons or a natural person by processing of data, where such processing aims to evaluate certain personal aspects relating to him and, in particular, his efficiency at work, his financial solvency, his credibility and his behaviour in general. Medical data does not appear to be included.

Right to compensation.

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According to section 17 of the Data Protection Law, 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 is not responsible for the event that caused the damage.

What about the data subject's rights and further processing for scientific research purposes?

Consent of data subject

As mentioned above, section 5 of the Data Protection Law provides the right to a data subject to give his unambiguous consent in order for the processing of his personal data to be lawful, with the exception, inter alia, that processing is necessary for compliance with a legal obligation to which the controller is subject (i.e. obligation of controller to provide data to the Statistical Service upon request. For sensitive data, no consent is required where the processing is carried out for statistical, research, scientific and historical purposes according to the decision of the Commissioner and provided that all necessary measures are taken to protect data subjects (section 6).

Furthermore, according to the Code of Practice for the Collection, Publication and Storage of Statistical Data, the consent to the data subject is also required for publishing or disseminating aggregated data where the number of statistical units (data subjects) is less than three.

Right to privacy and confidentiality

The Statistics Law provides for the confidentiality of statistical data (section 13) according to which, the data collected and processed by the Statistical Service for the production of statistics are considered as confidential as long as they allow the direct or indirect identification of statistical units and disclose personal data. The statistics compiled on the basis of the data resulting from a survey shall be published in such a manner as to render impossible the direct or indirect disclosure of the identity of those who provided the data or of the persons to whom the data relate.

Right of information of data subject

As mentioned above, the right of the data subject to be informed does not apply, especially in cases where the processing is performed for statistical and historical purposes or for purposes of scientific research if it is impossible to inform the data subject or where disproportionate effort is necessary in order to inform him, or if the communication of data is provided by another law, provided that in each case a license is issued by the Commissioner.

Where the Statistics Law is concerned, according to section 11 thereof, the officers of the Statistical Service have the obligation to inform the person from whom the provision of data is required about the conduct of a survey or work by virtue of this Law, the purpose of the survey or work, statistical confidentiality and the penalties imposed in case of refusal of provision of data or of provision of false, incomplete or inaccurate data.

Rights of the patient regarding medical records

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According to section 18 of the Patients' Rights Law, a patient has the right to be informed of, to have access to and to object to, data relating to him, which is contained in the medical records and, in the exercise of these rights, the provisions of sections 11 to 14 of the Data Protection Law shall apply, mutatis mutandis.

The patient's right of access to his medical records shall enable him, directly or indirectly through his legal representative, to receive information contained in these records, or a copy or extract thereof. This right includes the rectification of this information, their erasure and the blocking of the records by reason of inaccuracies and shortages.

The right of access may, however, be limited, rejected or suspended by the person for the time being responsible for keeping such medical records if, inter alia, information on third parties may be disclosed and it is impossible to prevent access to such information (such as in the case where the Statistical Service requires such records which must be given to it in accordance with the Statistics Law).

Patients' Rights Officer and Complaints Examination Committee for the safeguarding of the patients' rights in a State hospital.

According to section 22 of the Patients' Rights Law, every State hospital has a duty to designate a Patients' Rights Officer who is responsible for the safeguarding of the patients' rights and whose duties include giving advice and assistance to the patients for the purpose of safeguarding of the rights provided under this Law and receiving and handling complaints of patients. A Complaints Examination Committee is also established examine complaints of patients referred to it by the Patients' Rights Officer. As a result, where a medical institution provides information to third parties or to the Statistical Service, the data subject can apply to the above bodies for complaints handling.

4. The GDPR's impact on the current regulatory framework for the processing of health data for research purposes

a. The impact of the GDPR on the rules applying to processing for research in the field of health

Please provide a summary of the main relevant characteristics of the new law/Bill (as far as it is relevant for processing health data for research purposes). How is (or will be) Article 9(2)(j) implemented in your country?

The relevant provisions of the Draft Bill of Law regarding the processing of health data for research purposes are included mainly in Part IX of the Bill entitled *'Special Treatment'*, sections 27 to 29. It should be noted that the relevant provisions are rather limited and/or too general and difficult to interpret without any further interpretation by the competent authority. It should also be noted that the Bill no longer contains any provisions on sensitive data but refers to special categories of data as per the GDPR.

More specifically, according to section 27 entitled '*Processing and freedom of expression and information*' the processing of personal data or special categories of personal data (which, according to Article 9 of the GDPR incudes

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genetic data, biometric data for the purpose of uniquely identifying a natural person, data concerning health), which is carried out, inter alia, for journalistic, literary or academic purposes, is lawful, provided that these purposes are proportionate to the objective pursued and respect the essence of the rights laid down in the Charter of Fundamental Rights of the European Union, the European Convention on Human Rights and Fundamental Freedoms (ECHR) and Part II of the Constitution.

Section 29 entitled '*Safeguards and derogations relating to processing for archiving purposes in the public interest or for scientific or historical research or statistical purposes*' is the most relevant in this field and provides that the processing carried out by a data controller or processor for archiving purposes in the public interest or for scientific or historical research or statistical purposes, preclude the use of personal data with a view to adopting a decision which produces legal effects vis-à-vis the data subject or which significantly affects the data subject in an equivalent manner.

The above provision is not very clear and has not yet been analysed by any authority but appears to suggest that personal data must be anonymised so as not to produce legal effects vis-à-vis the data subject nor significantly affect the data subject.

b. Modification to the processing authorisation procedure applying to research in the field of health

How will the processing authorisation procedure (if any exists) be affected by the implementation of the GDPR? Can you describe any such change?

A permit from the Data Protection Commissioner will be required for the combination of archiving systems of public authorities or bodies in accordance with section 8 of the Bill. According to this section, the combination of large scale filing systems of two or more public authorities or organisations, shall only be permitted if an impact assessment is conducted jointly by the public authorities or bodies which will combine their filing systems and must contain certain information and, where appropriate, a description of the technical and organisational security measures referred to in the GDPR. The Commissioner may permit the combination of such large scale filing systems and impose terms and conditions on public authorities or bodies for the combination of their filing systems.

Furthermore, in accordance with section 11 of the Bill which falls under Part IV of the Bill entitled '*IMPACT ASSESSMENT WHEN DRAWING UP LEGISLATIVE MEASURES*', where any Law or Regulation issued under any Law, provides for a specific processing operation or a set of processing operations, an impact assessment and a prior consultation with the Commissioner will be required. This will not apply if the Commissioner deems that the Impact Assessment that was carried out is satisfactory and does not require the carrying out of an additional impact assessment, prior to the implementation of the operation concerned or set of processing operations.

Further to the above, it is not clear whether the above provisions relate to research in the field of health, apart from the case where a combination of filing systems will be made between two public authorities or a new Law will be issued by the Republic. As a result, the general provisions of the GDPR will apply, especially due to the fact that the Bill does not contain any specific authorisation procedures regarding this field.

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Another relevant provision, which has a more general application and thus may also apply to research in the field of health, is that contained in section 9 of the Bill entitled '*restriction of rights*' according to which, subject to the provisions of Article 23(1) of the GDPR, the data controller may apply measures to restrict the rights referred to in Articles 12 and 15 to 22 of the GDPR in whole or in part, on condition that an impact assessment is carried out and upon prior consultation with the Commissioner. The said impact assessment must contain the information referred to in Article 23 (2) and Article 35(7) of the GDPR and, where appropriate, a description of the technical and organisational security measures referred to in Articles 24, 25, 28 and 32 of the GDPR. The controller or processor is also required to inform the data subject of the implementation of the measures referred to above.

What about the right of the data subject and the obligations of the controller?

The Bill does not contain any general reference to the obligation to individually inform the person for whom or about whom the data has been collected. The provisions of the GDPR will apply in this respect. The only reference contained in the Bill regarding the provision of information to the data subject concerns the obligation of the data controller or processor to inform the data subject of the implementation of the technical and organisational security measures referred to in Articles 24, 25, 28 and 32 of the GDPR.

5. Further processing for research purposes under the GDPR

The notion of further processing under the GDPR:

The particularities of scientific research: a presumption of purpose compatibility

Given the regime applied to further processing in the GDPR, can you describe the consequences, if any, in your national legal framework?

The Draft Bill of Law defines 'processing' in exactly the same manner as the GDPR. There is no definition in the Bill as to further processing nor any other relevant provisions in this respect. As a result, the general provisions of the GDPR will directly apply.

6. Health data sources for research purposes

a. Sources of data and their regulation

Does your national framework contain specific provisions for anonymised or pseudonymised health data?

According to the definition of "*personal data*" given by the Data Protection Law, personal data means any information relating to a living data subject. Consolidated data of a statistical nature, from which the data subject

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cannot be identified, are not deemed to be personal data. As a result, aggregated or anonymized or pseudonymised data from which the data subjects can no longer be defined are not considered personal data.

The Data Protection Law also requires that where personal data is collected and processed by the data controller, such data must be accurate and, if necessary, kept up to date (section 4). Furthermore, data must be kept in a form that permits the identification of data subjects only for the period of time necessary for the fulfilment of the purpose for which the data is collected and processed. After the expiry of this period, the Data Protection Commissioner may, by a reasoned decision, allow the preservation of personal data for *historical, scientific, or statistical purposes*, if the Commissioner considers that in each specific case, the data subjects' rights or the rights of third parties are not affected

Furthermore, the Patient Rights Law provides that if the data is anonymised, it can be used, without consent, for publication in medical journals, teaching, etc. More specifically, according to section 15 of the Law under certain conditions the medical institution or the competent health care services provider may disclose medical information to a third party. According to section 15 (2) this is possible, if the disclosure of information is for the purpose of publication in medical journals or for research or teaching purposes, provided that all information identifying the patient is not disclosed.

The Statistics Law provides for the confidentiality of statistical data (section 13) according to which, the data collected and processed by the Statistical Service for the production of statistics are considered as confidential as long as they allow the direct or indirect identification of statistical units and disclose personal data. The statistics compiled on the basis of the data resulting from a survey shall be published in such a manner as to render impossible the direct or indirect disclosure of the identity of those who provided the data or of the persons to whom the data relate.

What are the different sources of health data that can be used for research purposes?

- **DIRECT COLLECTION FROM PATIENTS:**

Under the current legal framework: please explain the currently applying rules that a researcher, who intends to collect health data directly from individuals (e.g. via a survey, or by asking patients to wear a monitoring device, etc.), should follow.

As mentioned above, section 5 of the Data Protection Law provides the right to a data subject to give his unambiguous consent in order for the processing of his personal data to be lawful, with the exception, inter alia, that processing is necessary for compliance with a legal obligation to which the controller is subject (i.e. obligation of controller to provide data to the Statistical Service upon request.

For sensitive data such as health data or data concerning health, in principle, its processing is generally prohibited. However, this prohibition does not apply to processing for scientific research purposes under section 6 of the Data Protection Law. More specifically, no consent is required where the processing is carried out for statistical, research, scientific and historical purposes according to the decision of the Commissioner and provided that all necessary measures are taken to protect data subjects and their privacy (section 6).

With regards to the collection of data from the data subjects themselves through surveys and medical trials, the Patients' Rights Law contains specific provisions on the participation of patients in scientific research or experimental

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treatment (section 14(1)). The participation of a patient in scientific research or experimental treatment shall be allowed only in the following circumstances:

(f) there is no alternative solution of comparable effectiveness;

(g) the risks which may be incurred by that patient are not disproportionate to the potential benefits of the research;

(h) the research project has been approved by the competent body after independent examination of its scientific merit, including assessment of the importance of the aim of the research and multi-disciplinary review of its ethical acceptability;

(i) the patient has been informed of his rights prescribed by this Law;

(j) the necessary written consent of the patient provided for under section 13, has been given specifically and in writing after a complete medical information

According to section 14(2), where the patient is not able to consent, research may be undertaken only if the following conditions are met:

(a) the conditions mentioned in paragraphs (a) to (d) of subsection (1) of section 14(1) are met;

(b) the results of the research have the potential to produce real and direct benefit to his health;

(c) research of comparable efficiency cannot be carried out on individuals capable of giving consent;

(d) the necessary authorization provided for in section 13 of the Law has been given specifically and in writing; and

(e) the person concerned does not object.

Where Clinical Trials are concerned, all clinical trials are authorized to begin only upon approval by the National Bioethics Committee and the National Health Authority (Drugs Council). The consent of the patient must be obtained by means of a Consent Form for Participation in a Research Study.

The Cyprus National Bioethics Committee has also adopted the "Operational Guidelines for Ethics Committees that Review Biomedical Research"[9] formulated by the World Health Organization, to form the basis of the guidelines issued to the Cyprus Ethics Committees. These concern the ethical and scientific standards for carrying out biomedical research on human subjects. Ethics Committees are responsible for establishing well-defined requirements for submitting an application for review of a biomedical research project. An application for review of the ethics of proposed biomedical research should be submitted by a qualified researcher responsible for the ethical

9 http://www.bioethics.gov.cy/Moh/cnbc/cnbc.nsf/All/E3C3BC7D33CEADF7C2257CCA003B43C3?OpenDocument

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and scientific conduct of the research. The application should be submitted by completing specific forms established by the Cyprus National Bioethics Committee.

According to the Medicinal Products of Human Use (Good Clinical Practice) Regulations, patients involved in research must be informed by their doctor of the aspects of care related to the trial and they must also give their informed consent that they voluntarily wish to participate in the trial by signing relevant documentation. Nevertheless, the Regulations contain certain exceptions to the obligation to provide consent, e.g. where an authorisation is given by the Cyprus National Bioethics Committee, etc. (section 13). The Regulations also contain provisions as to the confidentiality of personal data collected during the trial

With regards to vulnerable subjects who are potentially to be involved in a clinical trial, their informed consent is obtained via their legal representative on the basis of the Medicinal Products of Human Use (Good Clinical Practice) Regulations. The legal representative must have the opportunity, in a prior meeting with the investigator or a member of the investigating team, to understand the objectives, risks and inconveniences of the trial, and the conditions under which it is to be conducted and has also been informed of his right to withdraw from the trial at any time. Then the legal representative of the participant will give his written consent after being informed about the nature, significance, implications and risks of the clinical trial (section 11). In case of minors, the informed consent of the parents or the legal representative is obtained, but consent must represent the minor's presumed will and may be revoked at any time, without detriment to the minor. Additionally the principal investigator or a member of the investigating team must give to the minor information according to its capacity of understanding, regarding the trial, the risks and benefits. Also, the explicit wish of a minor who is capable of forming an opinion and assessing this information to refuse participation or to be withdrawn from the clinical trial at any time is considered by the investigator or where appropriate the principal investigator (section 12).

Under the revised legal framework: will the currently existing procedures and rules change in view of the implementation of the GDPR in your country?

The Draft Bill of Law does not contain any specific provisions on health data sources for research purposes. As a result, the general provisions of the GDPR will directly apply.

The only relevant provisions of the Draft Bill of Law regarding the processing of health data for research purposes are included mainly in Part IX of the Bill entitled *'Special Treatment'*, sections 27 to 29. It should be noted that the relevant provisions are rather limited and/or too general. It should also be noted that the Bill no longer contains any provisions on sensitive data but refers to special categories of data as per the GDPR.

More specifically, according to section 29 of the Bill entitled '*Safeguards and derogations relating to processing for archiving purposes in the public interest or for scientific or historical research or statistical purposes*' processing carried out by a data controller or processor for archiving purposes in the public interest or for scientific or historical research or statistical purposes, preclude the use of personal data with a view to adopting a decision which produces legal effects vis-à-vis the data subject or which significantly affects the data subject in an equivalent manner.

- **COLLECTION FROM HEALTH PROFESSIONALS AND HEALTH INSTITUTIONS**

Under the current legal framework: please explain the rules currently applying that a researcher, who intends to obtain health data from medical staff, hospitals, etc., should follow.

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With regards to health data obtained from health care services providers, the provisions of the Patients' Rights Law is relevant which provide for the medical records kept for patients and which may be disclosed for scientific and research purposes subject to the conditions foreseen by the law as to confidentiality.

As mentioned above, "medical records" means any records compiled in written, electronic, or any other form, comprising information relating to the physical or mental health or condition of a patient whose identity may be determined thereby, and which are compiled by or on behalf of a person who by profession provides health care services (section 2).

Processing for scientific research purposes under section 6 of the Data Protection Law may be permitted without the consent of the data subject where the processing is carried out for statistical, research, scientific and historical purposes according to the decision of the Commissioner and provided that all necessary measures are taken to protect data subjects and their privacy (section 6).

Furthermore, according to section 15 of the Patients' Rights Law under certain conditions the medical institution or the competent health care services provider may disclose medical information to a third party. According to section 15 (2) this is possible, if:

(a) the patient has given his/her written consent. The patient's consent may be presumed, where disclosure is to a person involved in the patient's treatment;

(b) the disclosure is for the purpose of the patient's treatment by another health care service provider;

(c) the information is disclosed to the medical institution providing health care to the patient or to a member of its staff for the purposes of processing, or filing the information, or for notification required by law;

(d) the disclosure of information is *for the purpose of publication in medical journals or for research or teaching purposes, provided that all information identifying the patient is not disclosed;*

(e) there is a legal obligation to this effect;

(f) the Board of the Pancyprian Medical Association has decided, after giving both the medical practitioner and the patient an opportunity to express their views, that the non-disclosure of the information could possibly cause serious harm to other persons´ health or physical integrity or have serious impact to the society as a whole.

When information is being disclosed to the extent that the case requires, every effort shall be made to keep the identity of the patient secret.

It should also be mentioned that according also to section 17 of the Law, the competent health care services provider keeps medical records showing the course of the treatment of the patient. These records include detailed data identifying the patient and the competent health care services provider, as well as medical information on the treatment received by the patient, his previous medical record, as far as known, the diagnosis of his current medical condition and the treatment currently provided. Such data may be provided without the consent of the data subject

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where the processing is carried out for statistical, research, scientific and historical purposes according to the decision of the Commissioner and provided that all necessary measures are taken to protect the confidentiality of data subjects.

It should also be noted that according to the Code of Practice for the Collection, Publication and Storage of Statistical Data, the consent to the data subject is also required for publishing or disseminating aggregated data where the number of statistical units (data subjects) is less than three. If data subjects are more than three and included in a research, no consent is required.

- **UNDER THE REVISED LEGAL FRAMEWORK:**

will the currently existing procedures and rules change in view of the implementation of the GDPR in your country?

The only relevant provisions of the Draft Bill of Law regarding the processing of health data for research purposes are included mainly in Part IX of the Bill entitled *'Special Treatment'*, sections 27 to 29. More specifically, according to section 29 of the Bill entitled '*Safeguards and derogations relating to processing for archiving purposes in the public interest or for scientific or historical research or statistical purposes'* processing carried out by a data controller or processor for archiving purposes in the public interest or for scientific or historical research or statistical purposes, preclude the use of personal data with a view to adopting a decision which produces legal effects vis-à-vis the data subject or which significantly affects the data subject in an equivalent manner.

The above provision is not very clear and has not yet been analysed by any authority but appears to suggest that personal data must be anonymised so as not to produce legal effects vis-à-vis the data subject nor significantly affect the data subject

Other than the above provisions, the general provisions of the GDPR will directly apply.

- **PRIVATE DATABASES**

Under the current legal framework: please explain the rules currently applying for the setting up of and the use of a private database with health data for research purposes.

The creation of private databases containing health data is not prohibited. The term private database could be a database created by a private medical institution/hospital/clinic which is not a public hospital/institution funded by the state or a database held by doctors, insurance companies and other private healthcare-related professionals. It could also include data collected and held by private universities and other private research facilities. It should be noted that at present, due to the lack of a General Health System or universal healthcare coverage system, there is a dual system of healthcare services – namely, the private system and the public system. The Private system comprises private clinics, private hospitals and independent doctors and physicians. The Public healthcare system consists of the 5 General Hospitals (one in each district), suburban outpatient departments, health centres, and rural health centres. Thus there is a distinction between the public and the private sector.

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Where the private sector is concerned, the Private Health Institutions Law contains a provision on the prohibition to reveal any information which constitutes a criminal offence in case of breach (section 24 of the Law). More specifically, no person can reveal any information obtained by means of the application of this Law.

Furthermore, the Law contains various provisions on the books and records that need to be kept by private hospitals/clinics (Part XI of Annex I). More specifically, every private health institute must keep, depending on the type and medical specialties provided, the following books/records:

(a) (i) Patient Registry, which records the full details of the patient's identity as well as the illness or pathological condition from which the patient is suffering or for which he / she has been admitted to the private health institute;

(ii) full details of minors' parents or guardian.

(b) A record of deceased patients, stating the date and cause of death, as well as the name of the physician certifying death.

(c) A medical report stating the medication taken by each patient.

(d) A surgical book, which is updated in detail by the head of the surgical team conducting surgeries in the health institute.

(e) Register of laboratory tests for each laboratory maintained at the health institute.

(f) Nursing Service Book

(g) Drug Repository.

(h) Individual patient files, fully up-to-date.

(i) Nursing Reference Form.

(i) Register of Accident and Emergency Situations Department (TAEP).

(k) An ambulance call form.

For maternity hospitals, the following is also added to the Patient Register:

(a) (i) The date of birth, the name of the doctor or midwife who was present and responsible for carrying out the childbirth, the sex of the child born if born or early born and if born alive or dead.

(ii) If the child was born alive, its state of health on the day of departure, and his date of departure from the health institute.

(iii) If the child died in the health institute, the date and cause of death.

(iv) If the mother died and the child survived, the name and address of the person who received the child and the relationship she may have with the child's mother.

(b) (i) The full name of the child's father and mother and, in the case of exorbitant, only the name of the mother.

(ii) Date and time of birth, weight at birth, if it is the first, second, etc. mother of the child.

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Where the use of private databases is concerned, section 7 of the Data Protection Law is also relevant in this respect. The controller who processes data for the purposes of entering data in private databases or for other processing purposes is discharged from the obligation to notify the data subject, in cases where, inter alia:

(a) processing is performed solely for purposes directly connected with the work to be done and is necessary for the fulfilment of a legal obligation or for the performance of a contract provided that the data subject has been previously informed,

(b) processing is performed by doctors or other persons who provide health services and concerns 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.

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.

Furthermore, according to section 10 of the Data Protection Law, for carrying out the processing, the controller must select persons who possess appropriate qualifications and who provide sufficient guarantees as regards technical knowledge and personal integrity for the observance of confidentiality. The controller must also take the appropriate organizational and technical measures for the security of data and their protection against accidental or unlawful destruction, accidental loss, alteration, unauthorised dissemination or access and any other form of unlawful processing. Such measures shall ensure a level of security which is appropriate to the risks involved in the processing and the nature of the data processed.

Under the revised legal framework: will the currently existing procedures and rules change in view of the implementation of the GDPR in your country?

The Draft Bill of Law does not contain any specific provisions on the setting up of and the use of a private database with health data for research purposes. The general provisions of the GDPR will directly apply.

- **PUBLIC DATABASES**

Under the current legal framework: do public authorities make available health data for research purposes in your country and under what conditions?

Public authorities make available health data mainly for statistical research purposes following a request by the Statistical Service. The Statistics Law provides for the confidentiality of statistical data (section 13) according to which, the data collected and processed by the Statistical Service for the production of statistics are considered as confidential as long as they allow the direct or indirect identification of statistical units and disclose personal data. The statistics compiled on the basis of the data resulting from a survey shall be published in such a manner as to render impossible the direct or indirect disclosure of the identity of those who provided the data or of the persons to whom the data relate.

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It should also be noted that according to the Code of Practice for the Collection, Publication and Storage of Statistical Data, the consent to the data subject is also required for publishing or disseminating aggregated data where the number of statistical units (data subjects) is less than three. If data subjects are more than three and included in a research, no consent is required.

The Patient Rights Law also provides that if the data is anonymised, it can be used, without consent, for publication in medical journals, teaching, etc. More specifically, according to section 15 of the Law under certain conditions the medical institution or the competent health care services provider may disclose medical information to a third party. According to section 15 (2) this is possible, if the disclosure of information is for the purpose of publication in medical journals or for research or teaching purposes, provided that all information identifying the patient is not disclosed.

Under the revised legal framework: will the currently existing procedures and rules change in view of the implementation of the GDPR in your country?

The Bill of Law contains a provision regarding the '*legality of certain transactions processing*' under Part II of the Bill. More specifically, according to section 5 of the Bill, the processing of personal data which is assigned by a Decision of the Council of Ministers to a public authority or body for the performance of a task carried out in the public interest or in the exercise of official authority, must be carried out in a lawful and fair manner, as well as in clear, precise and transparent manner in relation to the data subject in accordance with the provisions of Article 5(1)(a) and Article 6(1)(e) of the GDPR.

Furthermore, in accordance with section 8 of the Bill, the combination of large scale filing systems of two or more public authorities or organisations, shall only be permitted if an impact assessment is conducted jointly by the public authorities or bodies which will combine their filing systems and must contain certain information and, where appropriate, a description of the technical and organisational security measures referred to in the GDPR. The Commissioner may permit the combination of such large scale filing systems and impose terms and conditions on public authorities or bodies for the combination of their filing systems

The Draft Bill of Law does not contain any other specific provisions on public authorities making available health data for research purposes. The general provisions of the GDPR will directly apply.

b. Application of the national framework to the AEGLE cases

1. Type 2 diabetes

The operations realised in the AEGLE project which constitute processing for research in the field of health purposes are subject to the provisions of section 6 of the Data Protection Law which concerns the processing of sensitive data. As mentioned above, the collection and processing of sensitive data is permitted, when certain conditions are fulfilled, inter alia, where the processing is performed solely for statistical, research, scientific and historical purposes, on condition that all the necessary measures are taken for the protection of the data subjects including their confidentiality.

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At the time of collection of the data from the data subject himself, the controller must inform the data subject about the recipients or the categories of recipients and of the data. This is also the case where data is collected from third parties or where it is anticipated that the data will be communicated to third parties. Nevertheless, this obligation to inform the data subject does not apply where, especially in cases where the processing is performed for statistical and historical purposes or for purposes of scientific research if it is impossible to inform the data subject or where disproportionate effort is necessary in order to inform him, or if the communication of data is provided by another law, provided that in each case a license is issued by the Commissioner (section 11 of the Data Protection Law). Therefore, once access is granted to a database, before any processing of data commences, the authorisation of the Data Protection Commissioner must be provided by application of section 6 and 11 of the Data Protection Law.

Additionally, the Patients' Rights Law, section 15, provides for the ability to disclose to third parties of medical information by a medical institution or by a competent health care services provider. Such disclosure could be considered to be further processing. More specifically, a medical institution or a competent health care services provider may disclose medical information to a third person if, inter alia, the disclosure of information is for the purpose of publication in medical journals or for research or teaching purposes, provided that all information identifying the patient is not disclosed.

With regards to the GDPR, the provisions of section 29 of the Bill would apply according to which the processing carried out by a data controller or processor for archiving purposes in the public interest or for scientific or historical research or statistical purposes, preclude the use of personal data with a view to adopting a decision which produces legal effects vis-à-vis the data subject or which significantly affects the data subject in an equivalent manner. Even though the above provision is not very clear and requires a more specific interpretation by the competent authority, it appears to suggest that personal data must be anonymised so as not to produce legal effects vis-à-vis the data subject nor significantly affect the data subject.

2. Intensive Care Unit (ICU)

As mentioned in the Terms of Reference, AEGLE uses data generated by ICU devices without collecting the patient's consent (after pseudonymisation). This operation qualifies as processing for research in the field of health purposes and it is thus subject to the provisions of section 6 of the Data Protection Law which concerns the processing of sensitive data.

It is possible for health professionals to transfer the data they have collected in ICU services when they are treating patients to researchers without consent of the data subject to the rules of confidentiality and subject to a license granted by the Data Protection Commissioner. Therefore, once access is granted to a database, before any processing of data commences, the authorisation of the Data Protection Commissioner must be provided by application of section 6 and 11 of the Data Protection Law.

With regards to the GDPR, the provisions of section 29 of the Bill would apply according to which the processing carried out by a data controller or processor for archiving purposes in the public interest or for scientific or historical research or statistical purposes, preclude the use of personal data with a view to adopting a decision which produces legal effects vis-à-vis the data subject or which significantly affects the data subject in an equivalent manner. Even though the above provision is not very clear and requires a more specific interpretation by the competent authority, it appears to suggest that personal data must be anonymised so as not to produce legal effects vis-à-vis the data subject nor significantly affect the data subject.

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3. Chronic Lymphocytic Leukaemia (CLL)

As mentioned in the Terms of Reference the AEGLE project re-uses, after pseudonymisation, data coming from biobanks. In this instance, patients have given their informed consent for the samples and for the processing of their data. But this consent was given in general terms and not specifically for AEGLE.

This operation qualifies as processing for research in the field of health purposes and it is thus subject to the provisions of section 6 of the Data Protection Law which concerns the processing of sensitive data.

At the time of collection of the data from the data subject himself, the controller must inform the data subject about the recipients or the categories of recipients and of the data. This is also the case where data is collected from third parties or where it is anticipated that the data will be communicated to third parties. Nevertheless, this obligation to inform the data subject does not apply where, especially in cases where the processing is performed for statistical and historical purposes or for purposes of scientific research if it is impossible to inform the data subject or where disproportionate effort is necessary in order to inform him, or if the communication of data is provided by another law, provided that in each case a license is issued by the Commissioner (section 11 of the Data Protection Law). Therefore, once access is granted to a database, before any processing of data commences, the authorisation of the Data Protection Commissioner must be provided by application of section 6 and 11 of the Data Protection Law.

With regards to the GDPR, the provisions of section 29 of the Bill would apply according to which the processing carried out by a data controller or processor for archiving purposes in the public interest or for scientific or historical research or statistical purposes, preclude the use of personal data with a view to adopting a decision which produces legal effects vis-à-vis the data subject or which significantly affects the data subject in an equivalent manner. Even though the above provision is not very clear and requires a more specific interpretation by the competent authority, it appears to suggest that personal data must be anonymised so as not to produce legal effects vis-à-vis the data subject nor significantly affect the data subject.

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