'Big data analytics' and processing of health data for scientific research purposes : The Greek legal framework

Research Protocol by Ioannis Iglezakis,
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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.

- Law 2472/1997 on the protection of the Individual with regard to the processing of personal data[1].

This act transposed Directive 95/46 on the protection of individuals with regard to the processing of personal data and on the free movement of such data.[2] It is noteworthy that before the transposition of the directive, there was no law governing the protection of personal data in Greece. The Act was amended several times. It will be repealed with a new law on the implementation of the GDPR which will pass through the Parliament soon and it will be replaced by the GDPR and the provisions of the former act.

The GDPR implementing bill includes provisions on the processing of health data for research purposes, i.e., Article 19.

- Law 3172/2003 on the organization and modernization of public health services

This act defines public health and regulates public health services.

- Law 33702005 on the organization and management of public health services

This act regulates the general framework for the provision of health services by the state.

- EU Regulation 536/2014, Articles 28-34

This act provides protection of clinical trial subjects and in particular, it foresees that the rights of the subject to physical and mental integrity, to privacy and to the protection of the data concerning him

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[1] www.dpa.gr

[2] Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data.

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Shared electronic health records are indirectly relevant in this context because they can potentially be an important source for health-related research.

The patient's (electronic) medical file

Law 3418/2005 (Code of Medical Code of Conduct) in Article 14 provides for the obligation of medial doctors to keep medical files in electronic form (or non-electronic). Clinics and hospitals are also obliged to keep files and results of all clinic and paraclinical examinations. This provision also describes the content of medical files and provides that patients' data must be stored for ten years since the last visit of the patient and in any other case for twenty years.

The law prohibits access of third persons to patients' medical files, with the exception of judicial authorities, of state authorities having right to access and any third person invoking a legal interest. Thus, it does not include a clear right to exchange medical information with other professionals and such exchange can be based only on the exception of a particular legal interest.

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?

A bill for the implementation of GDPR has been prepared by an experts' committee and was given for public consultation[3]. Consultation was concluded on March 5, 2018, and several comments were submitted. The Minister of Justice will send the bill, after considering the comments, to the Parliament, and an act will be enacted.

The explanatory statement of the bill was not published during the public consultation, but it came to our attention that it is extensive document, explaining the rationale and the individual provisions of the bill. As already mentioned, the bill derogates Act 2472/1997 and includes provisions based on the delegatory powers provided by the GDPR in specific areas, such video surveillance, processing of workers' personal data, etc. The bill provides for a lower age of consent for minors, that is, 15 years of age.

Moreover, the Bill also transposes into national law EU Directive 2016/680 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data by competent authorities for the purposes of the prevention, investigation, detection or prosecution of criminal offences or the execution of criminal penalties, and on the free movement of such data.

[3] http://www.opengov.gr/ministryofjustice/?p=9331.

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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?

In Greece, the Data Protection Authority (DPA) is an independent administrative authority, which is modelled on the basis of the French authority (CNIL). In accordance with Article 7 (2) lit. g of Law 2472/1997 it has the authority to grant authorization for the processing of data for research purposes, including health data. The Authority is governed by the provisions of Articles 15-20 of the above act and Articles 9A and 101A of the Constitution.

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

Chapter IV of the Bill deals with the Greek DPA. It is established as an independent authority under the Minister of Justice, Transparency and Human Rights, not subject to any administrative or hierarchical control, with seat in Athens. The Bill implements the provisions of Chapter VI of the GDPR, which provides rules for supervisory authorities in EU Member States.

The Bill brings changes to the existing provisions of the Data Protection Act regarding the establishing, the powers and obligations of the Authority. According to Article 60 of the Bill, the DPA is responsible for monitoring the implementation of EU Regulation 2016/679, Directive 2016/680 and the present act. The DPA represents Greece in the European data protection board.

The DPA can issue guidelines and recommendations and propose best practices for any data protection issue. It can issue recommendations addressing to the Parliament, to the government or other public authorities and to the public for any data protection issue. It will provide recommendations to any new legislative act relating to data processing at the stage of public consultation. It shall also provide consultancy to data controllers according to article 36 GDPR, publish models and data breach notifications drafts, it approves certification criteria according to Article 42 GDPR and assists the national accreditation organization. It further controls the legitimacy of processing, it handles complaints by data subjects, it reports data protection infringements in the Parliament and drafts an annual report.

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.”

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a. Transposition of Article 8.4 of Directive 95/46

Under law 2472/1997 data relating to health are considered sensitive data (article 2 lit. b) and as such it processing is prohibited by Article 7 (1) of this act. This does not apply if one of several reasons apply, including the case where the data subject has given his/her written consent, or if the processing is concerning health issues and is carried out by a person engaged in the provision of health services and being subject to confidentiality, provided that processing is necessary for medical prevention, diagnosis, treatment of management of health services (Article 7 (2) lit. d), or the processing is carried out exclusively for research and scientific purposes, under the condition that anonymity is preserved and all necessary measures for the protection of the data subjects are taken (Article 7 (2) lit. f).

It is notable that health professionals are exempted from the obligation to be granted authorization for the processing of health data, provided that they are subject to medical secrecy or a similar duty (Article 7A (1) lit. d). Such an exemption is not provided for research purposes. The DPA has granted authorizations for research in health data and required the anonymization of personal data used[4].

Further than that, a research program must be approved by the competent Scientific Council and the Ethics Committee (article 24 (2) lid. d of Law 3418/2005).

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?

Research for health purposes, in general, is governed by the provisions of Law 3418/2005 (Medical Code of Conduct), Chapter VII. This act distinguishes between research on human beings (Article 24) and clinical research with new medicines and new therapeutic methods (Article 25).

Article 24 para. 1 of the Code enshrines the freedom of medical research[5], while para. 2 provides the requirements for a legitimate research on humans. These include the following conditions: i) informing the subject of research regarding a) the existence and the extent of possible risks, b) the individual's rights of protection, c) the voluntary nature of participation in the research, d) the right to revoke the consent, ii) free, without restrictions, specific and documented consent of the human subject, iii) that the risks to which a human is exposed are relatively small with regard to the possible benefits of the research and iv) that the research programme has been approved by the competent organ with the consenting opinion of the Scientific Council and Ethics Committee.

Article 25 of Medical Code of Conduct regulates clinical research with new medicine or new diagnostic and therapeutic methods, as mentioned above. Such research is allowed if all the above requirements are fulfilled and,

[4] See Ch. Latsiou, in: Kotsalis (ed.), *Personal Data*, 2016 (in Greek), 167.

[5] According to Article 24(1) of Law 3418/2005, medical research shall be carried out at liberty in the framework of fundamental ethical and moral values, which are characterized by respect to humans and to their dignity.

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if the clinical study is in line with general requirements set out by the EU and there is scientific evidence that their use or application will increase the chances of survival of restitution of health or relief of patients suffering from corresponding diseases.

A third category of health research is the non-therapeutic biomedical research for purely scientific reasons. Such research is permitted, in accordance with article 26 of the Medical Code of Conduct, provided that the requirements of article 24 are fulfilled and, in addition the following requirements: the medical researcher must regard as his/her duty the protection of life, health and dignity of a person, and such protection is preceding the interests of science or the society's interests, and should take necessary measure so that the participation of the individual in the research to take place without any payment.

Clinical trials are also governed by EU Regulation 536/2014. Previously, Ministerial Decision DYC3/89292 implemented Directive 2001/20 on the approximation of the laws, regulations and administrative provisions of the Member States relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use.

Regulation 536/2014 provides rules on the protection of subjects in clinical trials, whereby data protection rules are important to safeguard that consent is informed and freely given.

The research may take place only if the DPA has given an authorization, in addition to the above requirements.

The DPA has held that in the case of researchers requesting access to data files of a controller, it shall provide two authorizations: one to the controller who owns the data to provide the sensitive data, and one to the researcher who will receive those data for the purpose of scientific research[6]. The latter becomes, then, controller of the sensitive data for the purpose of scientific research[7].

Particularly, as far as the extraction of health data from hospitals for the purpose of carrying out scientific research is concerned, the concurring opinion of the Scientific council and Ethics Committee is required. It is notable that Law 3979/2011 requires the appointment of an internal data protection officer, who should be responsible for the implementation of the Data protection act, but this measure has not been implemented, and thus, there are no other safeguards but the authorization of the DPA.

The DPA has issued authorizations for scientific research to the Greek Health Institute, to Institutes of Faculty of Medicine of Athens and Thessaloniki to conduct specific research, and also to research teams of various Universities participating in research initiatives[8].

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

In Greece, there is no exemption for researchers, under the Data Protection Act.

[6] See DPA, decision 31/2013.

[7] See DPA Annual Report 2011, 62-63, 2012, 66, 2013, 66.

[8] See Latsiou, ibid, 168.

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Health professionals are solely exempted from authorization, insofar as they are bound by medical secrecy of other obligation for confidentiality and the personal data are not transmitted to any third parties.

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. The Greek Data Protection Act does not include an exception in favor of scientific research, it only allows the processing of sensitive data for such purpose, provided that anonymity is preserved, and the rights of data subjects are preserved.

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?

Personal information concerning health are subject to medical secrecy, in accordance with Article 13 Medical Code of Conduct[9]. The lift of medical secrecy is permitted where: a) a medical doctor aims at fulfilling a legal duty, i.e. declaring birth or death or when he/she is informed about an attempt of a crime, b) he/she aims at protecting a legal or other substantial public interest or his/her interest or another man's interest, or when c) an emergency emerges.

The medical secrecy can also be lifted with the consent of the subject, in accordance with Article 13 (4) Medical Code of Conduct. Consent should be written and in line with the requirements of the data protection act (see article 2 lit. h of Directive 95/46)[10].

Infringements of the duty of confidentiality are subject to criminal sanctions, according to Article 371 Penal Code. Such acts may not be sanctioned, however, if the perpetrator aimed at the fulfilling of a duty or preserving a legal or other substantial public or private interest.

The duty of medical secrecy does not cease with the death of the patient, in accordance with Article 13 (6) of the Medical Code of Conduct. An infringement of this obligation is subject to criminal charges and civil compensation for infringing the right to protection of personality (articles 57 (2) and 914 civil code).

There is no specific provision on the data of minors and the persons under guardianship. Thus, the general provisions of law apply, i.e. articles 127 et seq. Civil Code. According to the civil law provisions, the legal representative of the

[9] The obligation of medical confidentiality has been recognized since the oath of Hippocrates in 400 B.C.

[10] See E. Laskaridis, in: Commentary of the Medical Code of Conduct (in Greek), 2013, p. 166.

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minor or uncapable person can provide consent. However, a minor who is older than 10 years can provide consent if medical treatment is provided free (analogy from article 134 Civil Code).

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

The data subject must be informed about the processing of his/her health data, according to the provision of article 11 Data Protection Act, and there is no exemption from the right to information concerning data processing for scientific purposes.

However, in case the data subjects are abundant (more than 1,000), the data subjects are not informed individually, but can be informed through a publication in the press and in particular, by a publication in 2 newspapers circulating in the whole country, one daily and one Sunday publication, and also online[11].

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?

Article 21 of the Data Protection Act provides for administrative penalties in case of infringements of the law, which extend from a simple warning with an order to cease the violation to a fine amounting up to 146,000 Euro, as well as the – temporary or definitive – revocation of the authorization. Furthermore, article 22 of this act provides for criminal sanctions and article 23 for civil liability of the perpetrator.

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?

Under the Greek Data Protection Act, processing of personal data must be notified to the DPA, so that the DPA can set up a register of data processing (article 6 Law 2472/1997). Particularly, the processing of sensitive data such as health data for scientific purposes is subject to authorization by the DPA (article 7 (2) Law 2472/1997).

The authorization for the processing of sensitive data is issued for a specific period, depending on the purpose of the processing and may be renewed (article 7 (4)). The content of the authorization is described in article 7 (5).

Particularly regarding processing carried out for research and scientific purposes, it is required that data are anonymised. This required was clarified by decisions of the Greek DPA concerning the processing of patient's data in hospitals by the controller, i.e. doctors working in the hospital who were undertaking scientific research. The DPA granted an authorization under the following conditions: a) access to patients' data files should take place in the place where the files are stored; b) the applicants should extract only the necessary information from the patients'

[11] See Decision 1/1999 of the Greek DPA.

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files; and c) anonymization of patients' data should take place when access is granted to the sensitive data and before the publication or use of the research results[12].

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

Under the Greek Data Protection Act, the further use of personal data is not specifically regulated; thus, it is regarded as processing which must fulfil the requirements of legitimacy, according to general provisions. As mentioned above, the DPA requires that the controller of the data is granted an authorization and the researcher a second one.

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

Law 2472/1997 includes a regulation of 'further processing' in Article 4 (1) lit. d[13], but only as regards the retention of personal data for more than necessary. Further processing must be in line with the purpose of the processing for which the data was collected. According to the principle of purpose limitation (article 4 (1) lit. a), data must be collected for a defined purpose, and cannot be processed in a manner incompatible with this purpose.

According to general provisions of the data protection act, further processing must be compatible with the principles of data quality in Article 4 and the provisions on the legality of processing (articles 5 and 7). In case the purpose of further processing is different from the initial purpose of processing, the former should be based either on consent of the data subject or on the scientific or research purpose.

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

The processing of personal data for scientific research concerning health is dealt with in article 7 regulating sensitive data. This provision does not contain specific provisions related to further processing.

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

[12] See Decisions 46/2004, 47/2004, 32/2006, 54/2008, 63/2009, 10/2011, 121/2011.

[13] Article 4. 1. Personal data to be lawfully processed must:

a) be collected in a manner that is fair and legitimate for defined, explicit, and legitimate purposes, and be subject to a fair and legitimate processing for these purposes;

(b) be relevant, appropriate, and not more than is required at all times for the purposes of the processing;

c) Be accurate and, if necessary, be up-to-date;

(d) be kept in a form which permits the identification of their subjects only during the period required, at the discretion of the Authority, for the purposes of collecting and processing them. After this period, the Authority may, in a reasoned decision, authorize the retention of personal data for historical scientific or statistical purposes if it considers that the rights of its subjects or third parties are not affected in each particular case.

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The right to information is foreseen in article 11 of the Greek data protection act, applying to the collection of personal data by the data subject, but it also applies to data processing where data is not collected directly by the data subject, thus it applies to further processing, also. The controller must inform the data subject about: (a) the identity of the controller and of his representative, if any; (b) the purposes of the processing; (c) the recipient or the categories of recipients of data; and (d) the existence of the right to access.

There are no specific provisions regulating data subjects' rights in the above act, thus the provisions on the right to access and the right to object apply by analogy.

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

Since there is no derogation in case of processing for scientific research purposes, further processing is subject to the general provisions on the rights of data subjects.

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 Bill on the implementation of the GDPR includes a specific provision on the processing of personal data for the purposes of scientific or historical research or for statistical purposes, i.e. Article 19. The processing of specific categories of data, including health data, is regulated in para. 2. This provision provides that processing is permitted where: a) the data subjects have given their consent; b) the controller has already access to research data from previous scientific or statistical research and the data subjects have consented in further use or use for relevant purposes; or c) the controller is able to prove that processing is necessary for the purpose of scientific or historical research or for statistical purposes and the rights of data subjects are not overridden.

Particularly, when the processing for scientific or other purposes includes health data or genetic data the controller shall ensure that the processing should be carried out by persons which are subject to professional secrecy rules or confidentiality by a legal act.

An exemption from the rights of data subjects provided for in articles 15, 16, 18 and 21 GDRPR is provided in para. 11, if that creates obstacles or make it impossible to achieve the purposes of scientific or other purposes.

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

The authorisation procedure for the processing of specific categories of data is abrogated. The controller is obliged to carry out a data protection impact assessment (DPIA) in accordance with Article 35 GDPR. If a DPIA indicates that the processing would result in a high risk in the absence of measures taken by the controller to mitigate the risk, then, according to article 36 GDPR, the controller shall consult the supervisory authority prior to processing.

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

The Greek Bill implementing the GDPR does not provide for an authorization procedure. According to Article 13 of the Bill, the DPA may only be consulted in the following cases: a) where processing of health data and genetic data is carried out on a large scale for purposes in the public interest, such as electronic prescription systems, electronic patient files or health smart cards; b) where health data are processed at a large scale for the purpose of management of health and social security systems and services; c) on a systematic processing of genetic or biometric data at a large scale.

Particularly, as regards the processing for scientific purposes of specific categories of data, including health, Article 19 does not foresee any prior authorization with the exception of processing of genetic data at a large scale for scientific purposes (para. 4).

The GDPR certainly changes the logic of control, as practiced in Greece until recently, as it abolishes authorization. This allows the DPA to play its role as an administrative authority exercising control and imposing sanctions in cases of data protection infringements.

The Greek GDPR implementation Bill does not introduce any formal authorization requirements and in case of processing of special categories of data it introduces as additional safeguards a) the requirement of written consent, b) the prohibition of collection and processing of genetic data and the carrying out of genetic tests for the purpose of health and life insurance and c) the prohibition of processing of data resulting from diagnostic genetic tests related to member of the data subject's family.

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

The Bill provides for a derogation from the rights of data subjects established in articles 15, 16, 18 and 21 GDPR. Accordingly, the controller may deny with a justified decision those rights to the data subjects, to the extent and if they may render impossible or restrict the purposes of the scientific research. It is required, however, that the above restrictions of rights necessary to achieve those purpose are. Thus, the principle of proportionality must be satisfied.

The controller should inform the data exercising those rights that they are restricted, unless this information is detrimental to the purposes of the restriction.

In any case, the data subject may address to the DPA where his/her rights are restricted, and the DPA may examine whether the requirements for the restriction are fulfilled.

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5. Further processing for research purposes under the GDPR

The notion of further processing under the GDPR:

Further processing can be defined as "the processing of personal data for purposes other than those for which the personal data has been initially collected". Further processing is allowed only when its purpose is compatible with the purpose for which the data has been initially collected. Further processing for a compatible purpose of personal data is possible using the same legal basis as the one used for the initial processing. According to article 19 (2) lit. a of the GDPR implementing Bill, the processing of special categories of personal data for scientific purposes is permitted if the controller has already access to the data from previous scientific research and the data subjects have consented to further processing for compatible purposes.

How to measure the compatibility of purpose of the further processing:

Further processing for a purpose other than that for which the personal data has been collected is governed by Article 6 (4) of the GDPR. In particular this article tries to address how to measure whether or not the purpose of the further processing is "compatible". This is particularly relevant to big data analytics. Article 6 (4) establishes a test to measure such compatibility.

Where this processing is not based on the data subject's consent, or EU or Member State law, but on another legal ground, the controller will ascertain the compatibility of the processing's purpose with the initial purpose stated during the data collection. To do so the controller will take several elements into account, in particular: any link between the initial purpose and the further processing purpose, the context of the collection and the relation between the data subject and the controller, the nature of the data, in particular if it is considered to be sensitive data under Article 9 of the GDPR. The controller will also consider the possible consequence of further processing for the data subject and the existence of appropriate safeguards. If the result of the test is positive for the controller, and shows none of the elements have been significantly altered to make the further processing unfair or illicit, no further legal basis is necessary for the further processing. If this is not the case, then the further processing will have to rely on a separate legal basis.

If this test is successfully met, then the further processing is possible. However, it will be up to the data controller to demonstrate the compatibility of the purposes.

The particularities of scientific research: a presumption of purpose compatibility

However, the processing for scientific research purpose is an exception. Indeed, under Article 5 (1) (b) of the GDPR the compatibility of the processing purpose of further processing with the initial purpose of the collection is presumed under Article 89 (1). Here the GDPR establishes a presumption of compatibility of purposes for scientific research purposes. The reasoning behind this exception can be easily imagined. Scientific research is very often based on existing data, this is why allowing the processing of personal for different (if not incompatible) purposes is fundamental for scientific research.

This assumption made for the benefit of scientific research is linked to the derogation of the principle of data minimisation for scientific research purposes. However, this presumption is limited by some requirements, which

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are set out in Article 89(1) of the GDPR: the appropriate safeguards for the data subject's rights and freedoms, and ensured technical and organisational measures, such as pseudonymisation. Although a different scenario would require different technical and organisational measures to ensure the safeguards for the data subject's rights and freedoms. This is clearly indicated in recital 156 of the GDPR: "The further processing of personal data for (…) scientific (…) research purposes (…) is to be carried out when the controller has assessed the feasibility to fulfil those purposes by processing data which does not permit or no longer permits the identification of data subjects, provided that appropriate safeguards exist (such as, for instance, pseudonymisation of the data)."

Additionally, further processing of personal data is connected to the principle of storage limitation (Article 5(1)(e) of the GDPR), as it also constitutes a derogation to that principle, "personal data may be stored for longer periods insofar as the personal data will be processed solely for archiving purposes in the public interest, scientific or historical research purposes or statistical purposes in accordance with Article 89(1) subject to implementation of the appropriate technical and organisational measures required by this Regulation in order to safeguard the rights and freedoms of the data subject".

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

The rules set out by the GDPR will be directly applicable and the previous Data Protection Act will be repealed once the Bill is enacted by the Parliament and the GDPR enters into force.

Further processing is governed by the relevant provisions of the GDPR, that is, article 5 (1) lit. b, 6 (4), but also by article 19 of the Bill.

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?

In the current legal framework, article 7 (2) lit. f Law 2472/1997 provides that the processing of sensitive data for scientific purposes is permitted, provided that the data will be anonymized, and measures will be taken to protect the rights and freedoms of the persons concerned. There is no provision for the pseudonymization of data nor does the DPA impose such a restriction in such cases.

The Bill implementing the GDPR provides specifically for the processing of data for research purposes that if those purposes can be attained with anonymization or pseudonymization of personal data, then the controller may prefer the accomplishment of the research purposes via anonymization or pseudonymization, if the research purposes are not hindered through those methods.

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

- **DIRECT COLLECTION FROM PATIENTS:**

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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.

According to Article 7, the collection and processing of sensitive data is prohibited, but there are certain exceptions from the rule of prohibition, in which the DPA will issue an authorization of processing. One such exception is where processing takes place for research and scientific purposes[14]. The data subject from whom the data was collected must be informed of the following data: a) the identity of the controller and the identity of his/her representative, if any, b) the purpose of data processing, c) the recipients or the categories of recipients of such data, d) the existence of a right to access (Article 11 Law 2472/1997).

In case health data are collected by health professionals for the provision of medical treatment or for medical diagnosis or preventive medicine, and then the data is used for research purposes, the above provisions apply, as this is considered a further use of sensitive data, and the authorization from the DPA must be granted.

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

According to the Bill, the processing of personal data for purposes of scientific or historic research or for statistical purposes is governed by article 19, which complements article 89 GDPR. Particularly, the processing of special categories of data, which includes health data, is permitted where:

a) the data subjects have given their explicit consent; additionally, if this concerns the participation in scientific research in the framework of clinical trials on medicinal products, the provisions of article 28 to 34 of Regulation 536/2014 apply;

b) the controller has already access to research data from previous scientific or statistical research and the data subjects have consented in further use or use for relevant purposes; or

c) the controller can prove that processing is necessary for the purpose of scientific or historical research or for statistical purposes and the rights of data subjects are not overridden.

- **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.

Collection of health data by health professionals and health institutions for research purposes is governed by Article 7 (2) lit. f Data Protection Act, as mentioned above. The consent of the data subject is not necessary at that point, but authorization from the DPA must be obtained.

Additionally, the research project must be approved by the competent administrative organ, following a consenting opinion by the competent Scientific Council and the Ethics Committee, in accordance with article 24 (2) lit d Law

[14] Article 7 (2) lit f: "Processing is carried out exclusively for research and scientific purposes provided that anonymity is maintained and all necessary measures for the protection of the persons involved are taken".

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3418/2005. The researchers are, furthermore, subject to the obligation of professional secrecy, according to Article 13 (1) Law 3418/2005.[15]

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 does not substantially modify the conditions of access to data gathered by health professionals and health care establishments.

- **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 setting up and use of a private database with health data may only be permitted if processing will be carried out by a health professional subject to the obligation of professional secrecy or relevant codes of conduct and is subject to the condition that such processing is necessary for the purposes of preventive medicine, medical diagnosis, the provision of care or treatment or the management of health-care services. Additionally, the authorization by the DPA must be granted.

If the database is used for research purposes, the provision of article 7 (2) lit. f Law 2472/1997 applies, as mentioned above.

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 revised legal changes the conditions applying to the setting up of a private data base, in the sense that no authorization is needed by the DPA. The substantial requirements for carrying out the research are the same as before.

- **PUBLIC DATABASES**

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

In Greece, public authorities do not make available health data for research. Solely, the Greek Center for Disease Control & Prevention (HCDCP)[16] publishes annual, monthly and weekly statistic reports concerning epidemiologic research. However, the data included in those reports are of a statistic nature and they do not qualify as personal data according to article 2 lit. a Law 2472/1997.

[15] *"The physician must maintain absolute confidentiality for any information that he or she or the patient or third parties reveals to him or her in the performance of his / her duties and which concerns the patient or his / her family members".*

[16] http://www.keelpno.gr

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

Under the revised legal framework the rules applicable to the use of public databases do not effectively change.

b. Application of the national framework to the AEGLE cases

In the AEGLE project, the "research objective is to establish the use of Big data analysis in the prediction of outcomes in three working scenarios: Chronic Lymphotic Leukaemia (CLL), Intensive Care Units and type 2 diabetes for the prediction of adverse outcomes. The research methodology is Big Data analysis to establish predictive values that may apply in three clinical scenarios and to see if this can be generalised to other healthcare disease models". [17]

To achieve its objective, the AEGLE project must base its approach on the study, and thus the processing, of data concerning health. This section aims to address each of the three proposed AEGLE cases, and to determine the requirements in general terms for access and the processes relevant to data under the Directive (the current framework) and the GDPR.

1. Type 2 diabetes

The AEGLE project uses, after pseudonymisation, existing databases with health data collected from patients who expressed their consent to their data being used for research purposes.

The operations realised in the AEGLE project qualify as processing for research in the field of health purposes, thus, Article 7 of the data protection act applies.

Prior to processing, the DPA must grant an authorization. The application must be also submitted to the competent Scientific Council and the Ethics Committee, in accordance with article 24 (2) lit d Law 3418/2005, which must provide a consenting opinion.

If the data has been collected by health professionals during their activities, then they may transfer the data to researchers, provided that they are granted an authorization by the DPA, while the data recipient will be bound by professional secrecy for this data. In addition, the data subjects will have to be informed of the further processing of the data.

as concerns them, in the application of Article 32 (II) of the Act. However, if the further processing entails an anonymisation protocol, in application of CNIL's standards, then only the identity of the controller and the purpose of the processing must be communicated.

Once the GDPR has been implemented:

No authorization from the DPA is necessary. A DPIA must be carried out, thought, taking into count the provisions of article 19 (2) of the Bill. The DPA must be consulted in case the DPIA indicates that the processing would result in a high risk in the absence of measures taken by the controller to mitigate the risk.

[17] AEGLE Grant Agreement, Annex 1, p. 83.

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The consenting opinion of the competent Scientific Council and the Ethics Committee must be granted, also.

The rights of the data subjects must be respected. The persons concerned must be informed and they have the right to object to such processing or to obtain the erasure of data.

2. Intensive Care Unit (ICU)

AEGLE uses data generated by ICU devices without collecting the patient's consent (after pseudonymisation).

The operation realised in the AEGLE project qualifies as processing for research in the field of health purposes, thus article 7 of Law 2472/1997 apply.

The data is collected by health professionals in ICU services when they are treating patients. The processing of such data for research in the field of health is lawful, if it serves a compatible purpose. The legal basis for the processing is article 7 (2) lit. f Law 2472/1997.

Furthermore, for health professionals can to transfer the data they have collected to researchers, however, the recipient must be bound to professional secrecy. Additionally, the data subjects will have to be informed about the transfer, and they may oppose it.

The processing must be authorized by the DPA and the competent Scientific Council and the Ethics Committee must grant a consenting opinion.

Once the GDPR has been implemented:

No authorization by the DPA is required. Since the data are pseudonymized, the processing will be lawful if the controller can prove that the research is necessary for the purposes of scientific research and the rights of the data subject are not affected. The opinion of the competent Scientific Council and the Ethics Committee must be granted, also.

The rights of the data subjects must be respected. The persons concerned must be informed and they have the right to object to such processing or to obtain the erasure of data.

3. Chronic Lymphocytic Leukaemia (CLL)

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.

The processing carried out in the AEGLE project has a scientific research purpose and as such is regulated by article 7 (2) lit. f Law 2472/1997. The purpose of research is compatible with the initial purpose of processing. However, the authorization from the DPA must be granted for further processing in the context of the AEGLE project, while the competent Scientific Council and the Ethics Committee must provide a consenting opinion.

Once the GDPR has been implemented:

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The research project must be able to prove that the processing is necessary for the purposes of scientific research and the rights of the data subject are not affected, and the opinion of the competent Scientific Council and the Ethics Committee must be also granted.

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