'Big data analytics' and processing of health data for scientific research purposes : the Romanian legal framework

Research Protocol by Magda Alexandru, for Buzescu Ca – Legal & Tax, 27 March 2018
in Bucharest, Romania, *27 March 2018 updated 30 July 2018*

Contents

Co-funded by the Horizon 2020 Framework Programme of the European Union under Grant Agreement nº 644906.

Partners
EXUS AE (Coordinator), ICCS, KINGSTON, CERTH, Maxeler Technologies Limited, UPPSALA UNIVERSITET, UNISR, time.lex, EUR, CHS, LOBA, PAGNI, GNUBILA FRANCE, NTU

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 No. 677 of 2001 on the Protection of Individuals with Regard to the Processing of Personal Data and the Free Movement of Such Data *(Legea Pentru Protectia Persoanelor cu privire la Prelucrarea Datelor Cu Caracter Personal si Libera Circulatie a Acestor Date),* hereinafter referred to as "**Data Protection Law**"[1] setsout the general requirements for the processing of health data.

The Data Protection Law governed the collection and the processing of personal data, and it transposed the 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]. The Data Protection Law was amended twice in 2005 and 2007, however these amendments had no impact on the subject matter of this Report.

On June 24, 2018, the Law no. 129 of 2018 amending the Data Protection Law and the Law no. 102 of 2005 regarding the Setting Up, Organization and Operation of the National Supervisory Authority for Personal Data Processing ("**Law no. 129**")[3], entered into force on May 25, 2018. As a consequence, the Data Protection Law was repealed as expressly provided by the Law no. 129 due to the entry into effect of the REGULATION (EU) 2016/679 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data and repealing Directive 95/46/EC ("**GDPR**").

The healthcare legislation does not mention special rules regarding the processing of the health-related personal data but it merely provides general references to the general applicability of the provisions of the Data Protection Law, in relation to the health data processing, i.e.:

Law No. 95 of 2006 regarding Reform in the Healthcare Sector *(Legea nr. 95 din 2006 privind Reforma in Domeniul Sanatatii)* ("**Health Law**")

The Health Law governs the provision of health services. This voluminous document contains provisions on the rights of patients, illness prevention, but also on the administration of healthcare establishments.

[1] http://www.dataprotection.ro/servlet/ViewDocument?id=174

[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

[3] http://www.dataprotection.ro/servlet/ViewDocument?id=1502

Co-funded by the Horizon 2020 Framework Programme of the European Union under Grant Agreement nº 644906.

Partners
EXUS AE (Coordinator), ICCS, KINGSTON, CERTH, Maxeler Technologies Limited, UPPSALA UNIVERSITET, UNISR, time.lex, EUR, CHS, LOBA, PAGNI, GNUBILA FRANCE, NTU

The Health Law also provides that the Ministry of Health and its specialized structures have direct access and use to the data from the Health Insurance Information Platform, in compliance with the provisions of the Data Protection Law. Also, this law provides that the processing of the health-related personal data must be made in compliance with the Data Protection Law.

Law No. 46 of 2003 on the Patient's Rights *(Legea drepturilor pacientului)* ("**Patient's Rights Law**")

- The Patient's Rights Law provides that all patient status information, research results, diagnosis, prognosis, treatment, personal data are confidential even after his/her death. The confidential information may only be provided if the patient gives his/her explicit consent or if the law expressly requests it.

Generally, neither the Health Law nor the Patient's Rights Law provide specific sanctions for failure to comply with the privacy requirements applicable to the health data. As an exception, the Health Law expressly qualifies as criminal offence the disclosure by the employees of the health insurance companies of the insured persons' health condition in the absence of their consent.

Note:

As per the provisions of the Law no. 129, all the references to the Data Protection Law from the legislation enacted before the entry into force of GDPR will be considered as references to GDPR.

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: (Dosarul Electronic de Sanatate)[4]

The Health Electronic Record (EHR) is the Romanian national electronic health record which was implemented in Romania in 2014. EHR was developed and implemented in Romania by the National Health Insurance House ("**CNAS**")[5].

Pursuant to the general provisions of the Data Protection Law, the processing of health-related data is generally prohibited and it can be carried out only with the consent of the patient, or in the exceptional cases provided by Article 7 of the Data Protection Law, i.e.:

(i) when the processing is necessary in order to meet the obligations or specific rights of the data controller in the labour law sector, by observing the legal guarantees; a potential disclosure of the processed data to a third party can take place only if there is a legal obligation of the data controller in this sense, or if the data subject has expressly agreed to the disclosure;

[4] http://www.des-cnas.ro/pub/

[5] According to the Health Law, CNAS organizes and manages the Health Insurance Information Platform which consists of: the integrated health information system, the national system of the social health insurance card, the national system of electronic prescription and the system of the patient's electronic health record.

Co-funded by the Horizon 2020 Framework Programme of the European Union under Grant Agreement nº 644906.

Partners
EXUS AE (Coordinator), ICCS, KINGSTON, CERTH, Maxeler Technologies Limited, UPPSALA UNIVERSITET, UNISR, time.lex, EUR, CHS, LOBA, PAGNI, GNUBILA FRANCE, NTU

(ii) when the processing is necessary to protect the life, physical integrity or health of the data subject or of another person, when the data subject finds him/herself in a physical or legal incapacity to give his/her consent;

(iii) when the processing is carried out as part of the legitimate activities of a foundation, association, or of any other non-profit organization with a political, philosophic or trade-union profile, provided that the data subject is a member of that organization or has regular contacts with the organization in its activity profile, and provided that the data shall not be disclosed to a third party without the consent of the data subject;

(iv) when the processing refers to data made public in a clear way by the data subject;

(v) when the processing is necessary to determine, exercise or protect a right in a court of law;

(vi) when the processing is necessary for preventive medical care, to establish a medical diagnosis, to provide medical care and treatment in the interest of the data subject, or to administrate health services that are in the best interest of the data subject, subject to the fact that processing of that data is performed by or under the supervision of medical staff who is bound by professional confidentiality or by or under the supervision of another person subject to a similar obligation regarding the secrecy;

(vii) when the law states so in an express manner in order to protect an important public interest, subject to the fact that the processing is carried out in compliance with the rights of the data subject, and of other legal guarantees provided by the Data Protection Law.

Moreover, Article 9 of the Data Protection Law provides additional cases in which the prohibition to process the health-related data is not applicable, i.e.:

(i) if the processing is necessary for the protection of public health;

(ii) if the processing is necessary for the prevention of an imminent danger, the prevention of a criminal act, or for the prevention of the result of such an act or for the removal of the damaging results of such an act.

The processing of health data may be carried out only by, or under the supervision of medical staff who is bound by professional confidentiality, except for the cases when the data subject has given, in writing, his/her unequivocal consent and as long as the consent has not been withdrawn, as well as except for the cases when the data processing is necessary for the prevention of an imminent danger, the prevention of a criminal offence or of the consequences of such offence.

There are no other specific domestic rules regarding the consent of the patient to share data in relation to EHRs, in addition to the ones provided by the Data Protection Law.

Order No. 904 of 2006 regarding the Approval of the Norms referring to the Implementation of Good Practice Rules in the Conduct of Clinical Trials Performed with Pharmaceuticals for Human Use (*Ordinul nr. 904/2006 pentru aprobarea Normelor referitoare la implementarea regulilor de bună practică în desfăşurarea studiilor clinice efectuate cu medicamente de uz uman*) ("**Order No. 904**")[6], provides that the protection of the participants in a clinical trial is ensured by a risk assessment based on the results of toxicological tests prior to any clinical trial, through the control of Ethics Committees and the National Medicines Agency, as well as by the rules of personal data protection. However, the relevant provisions of all the above rules do not differ from the principles set out in

[6]https://www.anm.ro/en/_/ORDINE/Order%20of%20the%20Minister%20of%20Public%20Health%20no.%20903_25.07.2006%20and%20Annex.pdf

Co-funded by the Horizon 2020 Framework Programme of the European Union under Grant Agreement nº 644906.

Partners
EXUS AE (Coordinator), ICCS, KINGSTON, CERTH, Maxeler Technologies Limited, UPPSALA UNIVERSITET, UNISR, time.lex, EUR, CHS, LOBA, PAGNI, GNUBILA FRANCE, NTU

the Data Protection Law, since this special norm mentions references to the Data Protection Law. Also, Order no. 904 provides that the current legal norms are applicable without breaching the provisions of the Data Protection Law, and it transposes the Directive 2001/20/EC of 4 April 2001 on the harmonization of the laws, regulations and administrative provisions of the Member States relating to the implementation of good practice rules in the conduct of clinical trials on medicinal products for human use.

Order No. 1571 of 2010 for the Approval of the e-Romania and e-Health strategy and the implementation of the SIUI (Sole Integrated Information System) IT projects updated (on-line), the National Health Insurance Card, the e-Prescription and the Electronic Medical File **("Order no. 1571").**

This system consists of the following information:

(i) Summary of vital medical data - accessible in emergencies;

(ii) Complete medical history - a general view of the state of health;

(iii) History of the patient's medical history during the consultation;

(iv) History of medical records archived in chronological order;

(v) Secure and patient-readable personal data.

The Criminal Code: Codul Penal

The data protection legislation does not expressly set out criminal offences, but to the extent that the breaches of the said legal norms are committed under such conditions so as to represent criminal offences, the offender shall be criminally liable.

The Criminal Code governs criminal responsibility and the associated penalties concerning personal data, any breach of the obligations laid down. As per the provisions of Article 227 of the Criminal Code which provides that the unlawful disclosure of data or information on a person's private life which is likely to cause harm to a person by the person who has become aware of them by virtue of his profession or function and who is required to keep confidential about them shall be punishable by imprisonment from 3 months to 3 years or by fine.

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?

In addition to the Law no. 129[7] which provides for the repealing of the Data Protection Law, , another draft of the Law regarding the Implementation Measures for the Regulation (EU) 2016/679 on the Protection of Natural Persons with regard to the Processing of Personal Data and on the Free Movement of Such Data and Repealing Directive 95/46/EC was published on the website of the Romanian Senate on March 14, 2018 and further approved

[7] http://www.dataprotection.ro/servlet/ViewDocument?id=1502

Co-funded by the Horizon 2020 Framework Programme of the European Union under Grant Agreement nº 644906.

Partners
EXUS AE (Coordinator), ICCS, KINGSTON, CERTH, Maxeler Technologies Limited, UPPSALA UNIVERSITET, UNISR, time.lex, EUR, CHS, LOBA, PAGNI, GNUBILA FRANCE, NTU

by the Romanian Parliament, i.e. Law no. 190 of 2018 which was published in the Official Monitor no. 651 of July 26, 2018 ("**Law no. 190**")[8]

According to the Law no. 190[9], the processing of genetic, biometric or health data, in order to achieve an automated decision-making or profiling process, is permitted with the explicit consent of the data subject, or if the processing is carried out under explicit legal provisions, by establishing appropriate measures to protect the legitimate rights, freedoms and interests of the data subject. Moreover, the processing of health-related data for the purpose of assuring public health, as defined in the Regulation (EC) no. 1338 of 2008 of the European Parliament and of Council of December 16, 2008 on Community statistics on public health and health and safety at work ("**Regulation no. 1338**")[10] cannot be further processed for other purposes, by third party entities.

Also, the Law no. 190 provides that the processing of the health insurance number based on the legitimate interests purpose (Article 6 (1) (f) of the GDPR can be done by ensuring additional safeguards, including the appointment of a Data Protection Officer ("**DPO**").

The secondary legislation issued in the data protection field by the Romanian Data Protection Authority *Autoritatea Nationala de Supraveghere a Prelucrarii* Datelor *cu Caracter Personal* **("DPA")** before the entry into force of the GDPR was repealed by the Decision no. 99 of 2018 issued by the DPA.[11]

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?

The Romanian DPA is an autonomous authority and it is governed by the provisions of the Law no. 102 of 2005 regarding the Setting up, Organization and Operation of the National Supervisory Authority for Personal Data Processing ("**Law no. 102**") which was further amended by the Law no. 129.

As per the Decision no. 101/2008[12] regarding the Procedure of Issuing the Authorization for the Processing of Health-Related Personal Data ("**Decision no. 101**"), under the conditions of Article 9 paragraph 3 and 4 of the Data Protection Law, currently, the data controllers may process health-related data for the processing

[8] https://www.senat.ro/Legis/PDF/2018/18L294FP.pdf

[9] Article 3 https://www.senat.ro/legis/PDF/2018/18b094FG.pdf

[10] "public health" shall mean all elements related to health, namely health status, including morbidity and disability, the determinants having an effect on that health status, health care needs, resources allocated to health care, the provision of, and universal access to, health care as well as health care expenditure and financing, and the causes of mortality

[11] http://www.dataprotection.ro/servlet/ViewDocument?id=1497

[12] file:///C:/Users/Power/Downloads/decizia_nr._101_eng.pdf

Co-funded by the Horizon 2020 Framework Programme of the European Union under Grant Agreement nº 644906.

Partners
EXUS AE (Coordinator), ICCS, KINGSTON, CERTH, Maxeler Technologies Limited, UPPSALA UNIVERSITET, UNISR, time.lex, EUR, CHS, LOBA, PAGNI, GNUBILA FRANCE, NTU

of which the data subject did not give a written and unequivocal consent only after the prior filing of a notification and further obtaining of an authorization from the DPA.

Also, the Data Protection Law further provides that when the purposes of the processing refer to other people or to the general public, and the data subject has not given his/her written and unequivocal consent, the preliminary authorization of the DPA must first be demanded and obtained. The processing of personal data beyond the limits of the authorization is prohibited.

During the authorization procedure the data controller must file a new or an amended notification, if the case may be, together with the supporting documents, mentioning at least the following information, with the DPA:

1. the purpose of data processing;
2. the category(ies) of the data subjects;
3. the category(ies) of the processed personal data;
4. the estimated data for completion of the processing operation,
5. the collecting source of the personal data
6. the description of the data processing conditions and, where applicable of the reasons justifying the emergency.

Currently, the DPA no longer issues authorizations for the processing of the health data.

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

Given that the Data Protection Law was repealed as of May 25, 2018, as expressly provided by the Law no. 129, the notification regime disappeared and as a consequence no authorization is currently needed for the processing of the health-related data.

Moreover, Article I of the Law no. 129 provides for the powers of the DPA in view of the entry into force of the GDPR. The DPA activity is governed by the provision of Chapter VI of the GDPR (Articles 51 to 59). Article 54 of the GDPR provides that each Member State must set by law the rules establishing the supervisory authority. Accordingly, the Law no. 129 provides for the amendment of the articles regarding the DPA's powers.

Thus, the Law no. 129 mainly seeks to ensure the DPA's monitoring and control competences and tasks in accordance with the provisions of Article 55-59 of the GDPR. Thus, the DPA's main attributions are set, in line with the novelty elements brought by GDPR. The independence and autonomy of the DPA is also strengthened in accordance with the provisions of Article 52 of the GDPR.

In this context, the draft strengthens the obligation of the data controllers to grant the DPA, in the exercise of its legal powers, the required support, to make available the information or the documents they hold, based on the provisions of the law, in line with the investigation powers granted by Article 58 of the GDPR.

Co-funded by the Horizon 2020 Framework Programme of the European Union under Grant Agreement nº 644906.

Partners
EXUS AE (Coordinator), ICCS, KINGSTON, CERTH, Maxeler Technologies Limited, UPPSALA UNIVERSITET, UNISR, time.lex, EUR, CHS, LOBA, PAGNI, GNUBILA FRANCE, NTU

According to the Law no. 129, the authorized DPA's personnel may carry out investigations, in the cases and under the conditions set out by the law.

The DPA has the right to carry out investigations, including dawn raids, to seek and obtain from the data controller and as well as from the data processor, within a specific deadline, any information and documents regardless of the storage method, to take copies of them, as well as to check any equipment or data storage archive that is necessary to carry out the investigation.

Also, the DPA may decide to hear the persons whose statements are considered relevant and necessary for the conduct of the investigation. During the audit, the DPA may order corrective measures, including sanctions, to make recommendations and refer other competent authorities, as the case may be. In the case of joint operations carried out in Romania involving the personnel designated by another supervisory authority in a Member State of the European Union, it shall perform its tasks within the limits of their mandate issued by the President of the DPA.

Also, based on the Law no. 129, the DPA's President:

(i) can make proposals for the initiation of draft legal norms for the amendment of the existing legislation in areas related to the processing of personal data;

(ii) can ensure cooperation with similar foreign institutions and representation within the European Data Protection Committee provided for in Article 68 of the GDPR.

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?

Article 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

As a rule, health data may only be processed with the data subject's unequivocal consent. A limited number of exceptions to this rule were provided under the Data Protection Law and are provided under the Patient's Rights Law e.g. when the data are necessary to certified suppliers of medical treatment involved in the patient's treatment.

In case the processing was done without the data subject's written and unequivocal consent, an authorization was needed from the DPA for the processing of health data. Generally, the transfer of health data abroad was allowed with the data subject's unequivocal consent. If the transfer was made to countries not ensuring an adequate level of protection of personal data and the transfer was not grounded on a data transfer agreement based on the standard contractual clauses approved by the European Commission/Privacy Shield/BCR, the data subject's express written and unequivocal consent was necessary.

Co-funded by the Horizon 2020 Framework Programme of the European Union under Grant Agreement nº 644906.

Partners
EXUS AE (Coordinator), ICCS, KINGSTON, CERTH, Maxeler Technologies Limited, UPPSALA UNIVERSITET, UNISR, time.lex, EUR, CHS, LOBA, PAGNI, GNUBILA FRANCE, NTU

In Romania, data concerning health are a special category of personal data and their processing was prohibited by Article 7 of the Data Protection Law. However, this prohibition did not apply if the data subject has given his/her express consent, or when the processing is necessary for the purposes of preventive medicine, establishing medical diagnoses, administering medical care or medical treatment to the data subject or managing health services acting in the interest of the data subject, provided that such processing is carried out by or under the supervision of the medical staff subject to professional secrecy, or by/under the supervision of another person subject to an equivalent obligation of confidentiality (Article 7 (g)).

The prohibition to process health-related data provided by the Data Protection Law was also not applicable if the processing is necessary for the protection of public health or for the prevention of an imminent danger, the prevention of a criminal offence or the prevention of the result of such an action or for the removal of the damaging results of such an action.

According to the Data Protection Law, the processing of health-related data may be carried out only by, or under the supervision of, medical staff who are under a pledge of professional confidentiality, except for the cases when the data subject has given, in writing, his/her unequivocal consent and as long as the consent has not been withdrawn, as well as except for the cases when the data processing is necessary for the prevention of an imminent danger, the prevention of a criminal offence or the prevention of the result of such an action or for the removal of the damaging results of such an action.

The medical staff, health institutions and their staff may process personal health-related data without the authorization of the supervisory authority only when the data processing is required in order to protect the data subject's life, physical integrity or health. When the mentioned purposes refer to other people or to the general public and the data subject has not given his/her written and unequivocal consent, the preliminary authorization of the supervisory authority must first be demanded and obtained. The processing of personal data is forbidden beyond the limits of the authorization.

The personal health-related data may only be collected from the data subjects themselves. Exceptionally, these data can be collected from other sources only when it was required in order not to compromise the purpose of the processing, and when the data subject cannot or did not wish to provide them.

Also, the consent of the data subject was not required when the processing was done exclusively for statistical purposes, historical or scientific research, and the data remain anonymous throughout the processing (Article 5 (g)).

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 legal regime which was applicable to the processing of personal data for health research purposes was the general legal regime provided by the Data Protection Law and the Decision no. 101 issued by the DPA which is currently repealed by the Decision no. 88 of 2018 issued by the DPA.

Co-funded by the Horizon 2020 Framework Programme of the European Union under Grant Agreement nº 644906.

Partners
EXUS AE (Coordinator), ICCS, KINGSTON, CERTH, Maxeler Technologies Limited, UPPSALA UNIVERSITET, UNISR, time.lex, EUR, CHS, LOBA, PAGNI, GNUBILA FRANCE, NTU

All the clinical trials were subject to the Data Protection Law. As above-mentioned according to this legal norm, the personal health-related data were considered sensitive and their processing was prohibited, with several exceptions, without the data subject's express consent.

The personal health-related data may be processed only by or under the supervision of health professionals under conditions of professional secrecy.

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

The following exemptions provided by the Data Protection Law were also applicable to the researchers:

a. the consent of the data subject is not requested when the processing is made exclusively for statistical, historical and scientific research and the data are anonymous for the whole processing period[13].

b. at the end of the of the processing operations, if the data subject did not expressly and unambiguously give his/her consent for other data destination or for further processing, the personal data will be transformed into anonymous data and archived for statistical, historical and scientific research.[14]

c. when the data are not directly obtained from the data subject, the data controller must provide the data subject, at the time of the data collection or, if it is intended to be disclosed to third parties, at the latest by the time of the first disclosure, with the following information requested by the Data Protection Law[15], unless the data subject already possesses the following information:

(i) the identity of the data controller and, if required, of the data controller's representative;

(ii) the purpose of the data processing;

(iii) additional information, such as: the recipients, or the categories of recipients of the data; whether the requested information is compulsory, and the consequences of the refusal to provide it; the existence of the data subject's rights, provided by this law, namely the right of access, intervention and objection as well as the terms in which they may be exerted;

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

The above-mentioned information did not need to be provided when the processing of data was carried out for statistical, historical or scientific research, or in any other situations if providing such information proves to be impossible or would involve a disproportional effort towards the legitimate interest that might be damaged, as well as in the situations in which recording or disclosure of the data is expressly stated by the law.

[13] Article 5. (2) (g)

[14] Article Art. 6 (1)(c)

[15] Article 12 (4)

Co-funded by the Horizon 2020 Framework Programme of the European Union under Grant Agreement nº 644906.

Partners
EXUS AE (Coordinator), ICCS, KINGSTON, CERTH, Maxeler Technologies Limited, UPPSALA UNIVERSITET, UNISR, time.lex, EUR, CHS, LOBA, PAGNI, GNUBILA FRANCE, NTU

In Romania, the general notification regime also applied to scientific research. Thus, the data controller's obligations cannot differ from the general regime.

Consequently, the researchers were also subject to the general notification regime to the DPA.

As per the provisions of the Data Protection Law[16], each data subject had the right to obtain from the data controller, upon request, and free of charge, once a year, the confirmation of the fact that the data concerning him/her are or are not being processed by the data controller.

The data controller, in case it has processed any personal data concerning the data subject, was obliged to notify the data subject, with regard to the following:

a. information regarding the purposes of the data processing, the categories of data concerned, and the recipients or the categories of recipients to whom the data are to be disclosed;

b. notification in an intelligible form of the processed data and of any other available information regarding the source of origin of the respective data;

c. information on the technical principles and mechanisms involved in the data processing concerning that data subject;

d. information concerning the existence of the right of intervention upon the data, and the right to object, as well as the conditions in which the data subject can exert these rights;

e. information on the possibility of consulting the Register of Personal Data before filing a complaint with the DPA, as well as of filing a legal action against the data controller's decisions.

The data subject may request from the data controller the above-mentioned information through a written, dated and signed letter.

The data controller has the obligation to reply within 15 days as of the receipt of the letter. The above-mentioned letter may be filed by the data subject, or by the medical staff, appointed by the data subject, who will mention the person on whose behalf the request has been made.

If the personal health-related data are processed for scientific research purposes and such data are not used in order to take measures against a person, and the risk of infringing the rights of the data subject does not exist, the reply may be forwarded within a period of time exceeding 15 days, if that might affect the process or the outcome of the research, but it should not be delayed after the research has been completed. The delayed reply is allowed only if the data subject has given his/her express and unequivocal consent for the data to be processed for the purpose of scientific research, as well as for the possible delay of the reply.

[16] Article 13 (1)

Co-funded by the Horizon 2020 Framework Programme of the European Union under Grant Agreement nº 644906.

Partners
EXUS AE (Coordinator), ICCS, KINGSTON, CERTH, Maxeler Technologies Limited, UPPSALA UNIVERSITET, UNISR, time.lex, EUR, CHS, LOBA, PAGNI, GNUBILA FRANCE, NTU

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 authorized by the Member States for reasons of significant public interest, is subject to suitable safeguards.

The Data Protection Law provided an exception from the prohibition to process sensitive data, i.e. when the law expressly provides that the processing is done to protect a significant public interest under the condition that the processing is made by observance of the data subject's rights and all the other safeguards provided by the Data Protection Law.

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 data concerning health are protected by professional secrecy.[17]

Professional secrecy

The Data Protection Law[18] provides that the processing of personal data regarding the state of health is prohibited. However, an exception to this rule is applicable when the processing is required for preventive medical care, to establish a medical diagnosis, to provide medical care or treatment in the interest of the data subject, or to manage health services that are in the best interest of the data subject, on the condition that the processing of that data is performed by, or under the supervision of medical staff pledged to professional secrecy or by or under the supervision of another person subject to a similar obligation regarding the secrecy.

Also, the above-mentioned prohibition is not applicable to the processing of health data in the following situations:

a. if the processing is necessary for the protection of public health;

b. if the processing is necessary for the prevention of an imminent danger, the prevention of a criminal offence or the prevention of the result of such an action or for the removal of the damaging results of such an action.

[17] Article 9 (2) of the Data Protection Law

[18] Article 7 (1)

Co-funded by the Horizon 2020 Framework Programme of the European Union under Grant Agreement nº 644906.

Partners
EXUS AE (Coordinator), ICCS, KINGSTON, CERTH, Maxeler Technologies Limited, UPPSALA UNIVERSITET, UNISR, time.lex, EUR, CHS, LOBA, PAGNI, GNUBILA FRANCE, NTU

The processing of health-related data may be carried out only by, or under the supervision of, medical staff who are under a pledge of professional confidentiality, except for the cases when the data subject has given, in writing, his/her unequivocal consent and as long as the consent has not been withdrawn, as well as except for the cases when the data processing is necessary for the prevention of an imminent danger, the prevention of a criminal offence or the prevention of the result of such an action or for the removal of the damaging results of such an action.

Minors' regime

As per the provisions of the Decision no. 200 of 2015 Establishing the Cases of Personal Data Processing in which It Is Not Necessary to Submit a Notification, as well as on Amendment and Repealing Other Decisions ("**Decision no. 200**")[19]which was also repealed by the Decision no. 88 of 2018 issued by the DPA, the notification of the DPA was mandatory when the minors' personal data are processed by using the internet resources or the electronic messages.

Thus, in case the personal data of the minors are processed by using other methods than those

above-mentioned, the data controller has no obligation to file a notification with the DPA.

- As per the provisions of the Civil Code, the minor who has reached the age of 14 has limited exercise capacity. The legal acts of the minor with restricted capacity are concluded by him, with the consent of the parents or, as the case may be, of the guardian, and in the cases provided by the law, and with the authorization of the court. Approval or authorization may be given at the latest at the time of conclusion of the act. The minor who has not reached the age of 14 has no capacity of exercise, as a result, his/her legal acts are executed by the legal representative.

Deceased Persons' Regime

After the patient's death, his/her electronic health records are archived in the DES system and the contained data may be used in anonymized form, except where the legal provisions provide otherwise. Upon the expiry of the archiving period, the data contained in the electronic health records of the person in the DES system will be deleted or destroyed, as the case may be.

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

- In case the data are not obtained directly from the data subject, the data controller shall, at the time of the data collection or, if it is intended to be disclosed to third parties, at the latest by the time of the first disclosure, provide at least the following information to the data subject, unless the data subject already possesses the following information:

(i) the identity of the data controller and, if required, of the data controller's representative;

(ii) the purpose of the data processing;

(iii) the additional information, such as: the recipients, or the categories of recipients of the data; whether the requested information is compulsory, and the consequences of the refusal to provide it; the existence of the data

[19] file:///C:/Users/malexandru/Downloads/decizie_nr_200-2015._doc.pdf

Co-funded by the Horizon 2020 Framework Programme of the European Union under Grant Agreement nº 644906.

Partners
EXUS AE (Coordinator), ICCS, KINGSTON, CERTH, Maxeler Technologies Limited, UPPSALA UNIVERSITET, UNISR, time.lex, EUR, CHS, LOBA, PAGNI, GNUBILA FRANCE, NTU

subject's rights, stated by this law, namely the right of access, intervention and objection as well as the terms in which they may be exerted;

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

The above-mentioned information does not need to be provided to the data subject when the processing of data is carried out for statistical, historical or scientific research, or in any other situations if providing such information proves to be impossible or would involve a disproportional effort towards the legitimate interest that might be damaged, as well as in the situations in which recording or disclosure of the data is expressly provided by law.

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

Generally, failure to comply with the obligations under the Data Protection Law qualify as minor offence. Breaches of the obligations under the above-mentioned legal framework are sanctioned with administrative fines ranging from RON 500, i.e. approx. EUR 115 to RON 50,000, i.e. approx. EUR 11,500 under the Data Protection Law.

Furthermore, the DPA had the right to order the temporary or permanent termination/cessation of the processing of data conducted without the observance of all legal requirements. Also, the data subjects may request material or moral damages for prejudice generated by the unlawful processing of their personal data before the competent courts of law.

The data protection legislation does not expressly set out criminal offences, but to the extent that the breaches of the said legal norms are committed under such conditions so as to represent criminal offences, the offender shall be criminally liable.

Generally, neither of these legal norms provides specific sanctions for failure to comply with the privacy requirements applicable to health data.

The Health Law expressly qualifies as criminal offence, the failure to comply with good practice rules in the clinical trial of drugs which is punishable by imprisonment from one month to 6 months or by a fine.

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?

Co-funded by the Horizon 2020 Framework Programme of the European Union under Grant Agreement nº 644906.

Partners
EXUS AE (Coordinator), ICCS, KINGSTON, CERTH, Maxeler Technologies Limited, UPPSALA UNIVERSITET, UNISR, time.lex, EUR, CHS, LOBA, PAGNI, GNUBILA FRANCE, NTU

The notification regime changed in 2015, when the DPA issued the Decision no. 200, by which only the processing activities which may represent a risk need to be notified to the DPA.

Among these processing activities which need to be notified to the DPA are the processing activities related to health, sexual life, genetic and biometric data.

As per the Decision no. 200 if further to the receipt of a Notification filed with the DPA, the DPA ascertains that the processing is related to the above-mentioned data, it may decide to carry out a prior audit.

According to the Data Protection Law, the transfer of data and processing thereof can start within 5 days as of the uploading of the Notification, if the DPA does not inform the data controller that it will carry out this prior audit.

Please note that according to the Romanian legislation, the Notification must be updated every time the information included in the Notification is amended.

The notification regime of the health data is governed by the provisions of the Decision no. 101/2008[20] regarding the Procedure of Issuing the Authorization for the Processing of Health-Related Personal Data ("**Decision no. 101**"), currently, the data controllers may process health-related data for the processing of which the data subject did not give a written and unequivocal consent only after the prior obtaining of an authorization from the DPA.

The Data Protection Law provides that when the purposes of the processing refer to other individuals or to the general public, and the data subject has not given his/her written and unequivocal consent, the preliminary authorization of the DPA must first be demanded and obtained. The processing of personal data beyond the limits of the authorization is prohibited.

Except for emergency reasons, the authorization mentioned above may be given only after consulting the Romanian College of Physicians.

During the authorization procedure the following conditions must be fulfilled by the data controller:

a. the filing of a new or of an amended notification, if the case may be, with the DPA together with the supporting documents. mentioning at least the following information:

1. the purpose of data processing;

(ii) the category(ies) of the data subjects;

2. the category(ies) of the processed personal data;

(iv) the estimated date for the completion of the processing operation,

(v) the collecting source of the personal data

(vi) the description of the data processing conditions and, where applicable, of the reasons justifying the emergency.

Co-funded by the Horizon 2020 Framework Programme of the European Union under Grant Agreement nº 644906.

Partners
EXUS AE (Coordinator), ICCS, KINGSTON, CERTH, Maxeler Technologies Limited, UPPSALA UNIVERSITET, UNISR, time.lex, EUR, CHS, LOBA, PAGNI, GNUBILA FRANCE, NTU

Further to the entry into force of the Law no. 190, the legal regime of the processing of the health data is governed by Law no. 190 and according to the legal provisions of this implementation norm, there is no need to obtain an authorization from the DPA regarding the processing of the health data.

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

As per the Data Protection Law[21], upon completion of the processing operations, if the data subject has expressly and unequivocally given his/her consent for another destination or for further processing, the personal data shall be either destroyed, transferred to another data controller, provided that the data controller guarantees that the subsequent processing has purposes similar to those in which the initial processing was carried out or transformed into anonymous data and stored exclusively for statistical purposes, historical or scientific research.

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

The consent of the data subject for further processing is not requested when the processing is made for statistical, scientific or historical research purposes and the data are anonymized during the whole period of processing.

The personal data must be processed in good faith and according to the legal provisions in effect. Thus, the data must be collected for specific, explicit and legitimate purposes. Further processing of personal data for statistical, historical or scientific research, will not be considered incompatible with the initial purpose for collection of these data, if it is carried out according to the provisions of the Data Protection Law, including those referring to the notification regime, as well as according to the guarantees regarding personal data processing, mentioned by the legal provisions on statistics activity or the historical or scientific research.

Also, the data must be stored in such a manner that allows the identification of the data subject only for the time limit required to fulfil the purposes for which they are collected and further processed. The storage of data for a longer period of time than the one mentioned, for statistical, historical or scientific research purposes, shall be carried out in accordance with the guarantees regarding personal data processing, provided in the relevant legal framework, and only for the period of time required to achieve these purposes.

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

The Romanian legal framework does not provide for such specific conditions for further processing for scientific research in the field of health purposes.

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

Article 12 of the Data Protection Law sets out the data controller's obligation for processing and further processing.

In case the data were not obtained directly from the data subject, the data controller shall, at the time of the data collection or, if it is intended to be disclosed to third parties, at the latest by the time of the first disclosure, provide

[21] Article 6

Co-funded by the Horizon 2020 Framework Programme of the European Union under Grant Agreement nº 644906.

at least the following information to the data subject, unless the data subject already possesses the following information:

(i) the identity of the data controller and, if required, of the data controller's representative;

(ii) the purpose of the data processing;

(iii) additional information, such as: the recipients, or the categories of recipients of the data; whether the requested information is compulsory, and the consequences of the refusal to provide it; the existence of the data subject's rights, stated by this law, namely the right of access, intervention and objection as well as the terms in which they may be exerted;

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

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

The above-mentioned information does not need to be provided to the data subject when the processing of data is carried out for statistical, historical or scientific research, or in any other situations if providing such information proves to be impossible or would involve a disproportional effort towards the legitimate interest that might be damaged, as well as in situations in which recording or disclosure of the data is expressly stated by law.

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

a. The impact of 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-related data for research purposes). How is (or will be) Article 9(2)(j) implemented in your country?

According to the Law no. 190[22], the processing of genetic, biometric or health-related data for the purpose of automated decision-making or profiling is permitted with the explicit consent of the data subject, or if the processing is carried out under explicit legal provisions, by establishing appropriate measures to protect the legitimate rights, freedoms and interests of the data subject. Moreover, the processing of health-related data for the purpose of assuring public health, as defined in the Regulation no. 1338 cannot be further processed for other purposes, by third party entities.

[22] Article 3 (2)

Co-funded by the Horizon 2020 Framework Programme of the European Union under Grant Agreement nº 644906.

Partners
EXUS AE (Coordinator), ICCS, KINGSTON, CERTH, Maxeler Technologies Limited, UPPSALA UNIVERSITET, UNISR, time.lex, EUR, CHS, LOBA, PAGNI, GNUBILA FRANCE, NTU

Also, the Law no. 190 provides that the processing of the health insurance number based on the legitimate interests' purpose (Article 6(1) (f) of the GDPR can be done by ensuring additional safeguards, including the appointment of a DPO.

On September 2017, the DPA issued the Guidelines for the GDPR's implementation ("the **Guidelines**"). These Guidelines are in fact a summary of the GDPR and its implications for data controllers/processors, but these do not add much value for the GDPR's application in Romania. According to the Guidelines, the appointment of a DPO is mandatory under the conditions of Articles 37 – 39 of GDPR, in case the data controller or the data processor's main activity is to process sensitive data such as health, genetic and biometrical data on a large scale.

The DPA recommends the appointment of a DPO also in cases when such appointment is not mandatory according to the GDPR provisions by taking into consideration the beneficial effect of such appointment on ensuring the GDPR's compliance.

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

As per the Law no. 129, the Data Protection Law was entirely repealed and the provisions of the GDPR were directly applicable.

Given that the GDPR will be directly applicable, the prior notification regime is no longer applicable.

According to the DPA's Guidelines, a data protection impact assessment is mandatory when the health-related data are processed on a large scale. Also, when the results of the assessment indicate high risks, in the absence of measures taken to mitigate such risks, the controller must consult the DPA.

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

Given that the GDPR is directly applicable and there are no other legal norms issued with regard to the processing of the general health-related data or of the health-related data obtained during a research, there will be no notification procedure and consequently no authorization to be obtained.

There is no difference between health-related data and the health-related data obtained during a research.

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

Article 89 (2) of the GDPR provides the opportunity of derogations from: the right to access the data by the data subject, the right to rectify, the right to restrict the processing and the right to object. However, these derogations are only available if those rights would seriously impair or make impossible the scientific purpose of the processing.

The Law no. 190 does provide derogations from the rights of the data subject, i.e. Article 15 (right of access), 16 (right to rectification), 18 (right to restriction of processing) and 21 (right to object) of the GDPR are not applicable if the personal data are processed for scientific, historic research purposes or statistical purposes, to the extent that the above-mentioned rights referred are such as to make it impossible or seriously affect the achievement of the specific purposes and such derogations are necessary to achieve these purposes. These derogations are applicable only if adequate guarantees for the rights and freedoms of the individuals are ensured.

Co-funded by the Horizon 2020 Framework Programme of the European Union under Grant Agreement nº 644906.

Partners
EXUS AE (Coordinator), ICCS, KINGSTON, CERTH, Maxeler Technologies Limited, UPPSALA UNIVERSITET, UNISR, time.lex, EUR, CHS, LOBA, PAGNI, GNUBILA FRANCE, NTU

5. Further processing for research purposes under GDPR

The notion of further processing under GDPR:

Further processing can be defined as "the processing of personal data for purposes other than those for which the personal data have been initially collected". Further processing is allowed only when its purpose is compatible with the purpose for which the data have 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. For example, if personal data are initially processed based on the data subject's consent, then further processing for a compatible purpose is possible on the same legal basis. It is, in other words, not required to contact the data subject again for a new consent authorizing the further processing of the same data.

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

Further processing for a purpose other than that for which the personal data have 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 data 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 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 prove the compatibility of the purposes.

According to the Law no. 190[23], the processing of genetic, biometric or health-related data for the purpose of automated decision-making or profiling is permitted with the explicit consent of the data subject, or if the processing is carried out under explicit legal provisions, by establishing appropriate measures to protect the legitimate rights, freedoms and interests of the data subject. Moreover, the processing of health-related data for the purpose of assuring public health, as defined in Regulation no. 1338 cannot be further processed for other purposes, by third party entities.

The particularities of the scientific research: a presumption of purpose compatibility

However, the processing for scientific research purposes is an exception. Indeed, under Article 5 (1) (b) of GDPR the compatibility of the processing purposes of further processing with the initial purpose of the collection is presumed under Article 89 (1). Here, GDPR establishes a presumption of compatibility of purposes for scientific research

[23] Article 3

Co-funded by the Horizon 2020 Framework Programme of the European Union under Grant Agreement nº 644906.

Partners
EXUS AE (Coordinator), ICCS, KINGSTON, CERTH, Maxeler Technologies Limited, UPPSALA UNIVERSITET, UNISR, time.lex, EUR, CHS, LOBA, PAGNI, GNUBILA FRANCE, NTU

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 data 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 from the principle of data minimization for scientific research purposes. However, this presumption is limited by some requirements, which are set out in Article 89(1) of GDPR: the appropriate safeguards for the data subject's rights and freedoms, and ensured technical and organizational measures, such as pseudonymization. Although a different scenario would require different technical and organizational measures to ensure the safeguards for the data subject's rights and freedoms. This is clearly indicated in recital 156 of 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, pseudonymization of the data)."

Additionally, further processing of personal data is connected to the principle of storage limitation (Article 5(1)(e) of GDPR), as it also constitutes a derogation from 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 organizational 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?

According to the Law no. 190[24], the processing of genetic, biometric or health-related data for the purpose of automated decision-making or profiling is permitted with the explicit consent of the data subject, or if the processing is carried out under explicit legal provisions, by establishing appropriate measures to protect the legitimate rights, freedoms and interests of the data subject. The prohibition cannot be lifted by the consent of the data subject. Moreover, the processing of health-related data for the purpose of assuring public health, as defined in Regulation no. 1338 cannot be further processed for other purposes, by third party entities.

6. Health-related data sources for research purposes

a. Sources of data and their regulation

Does your national framework contain specific provisions for anonymized or pseudonymized health-related data?

In the current legal framework, the consent of the data subject is not required when the processing is done exclusively for statistical purposes, historical or scientific research, and the data remain anonymous throughout the processing (Article 5 (g)).

[24] Article 3

Co-funded by the Horizon 2020 Framework Programme of the European Union under Grant Agreement nº 644906.

Partners
EXUS AE (Coordinator), ICCS, KINGSTON, CERTH, Maxeler Technologies Limited, UPPSALA UNIVERSITET, UNISR, time.lex, EUR, CHS, LOBA, PAGNI, GNUBILA FRANCE, NTU

Also, at the end of the of the processing operations, if the data subject did not expressly and unambiguously give his/her consent for other data destination or for further processing, the personal data will be transformed into anonymous data and archived for statistical, historical and scientific research.[25]

What are the different sources of health-related 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-related data directly from individuals (e.g. via a survey, or by asking patients to wear a monitoring device, etc.), should follow.

Article 12 of the Data Protection Law sets out the rules with which the researchers must comply when collecting the health-related data:

In case the data are obtained directly from the data subject, the data controller must provide at least the following information to the data subject, unless the data subject already possesses the following information:

(i) the identity of the data controller and, if required, of the data controller's representative;

(ii) the purpose of the data processing;

(iii) additional information, such as: the recipients, or the categories of recipients of the data; whether the requested information is compulsory, and the consequences of the refusal to provide it; the existence of the data subject's rights, stated by this law, namely the right of access, intervention and objection as well as the terms in which they may be exerted;

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

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

According to the Law no. 190[26], the processing of genetic, biometric or health data for the purpose of automated decision-making or profiling is permitted with the explicit consent of the data subject, or if the processing is carried out under explicit legal provisions, by establishing appropriate measures to protect the legitimate rights, freedoms and interests of the data subject. The prohibition cannot be lifted by the consent of the data subject. Moreover, the processing of health-related data for the purpose of assuring public health, as defined in the Regulation no. 1338 cannot be further processed for other purposes, by third party entities.

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

[25] Article Art. 6 (1)(c)

[26] Article 3

Co-funded by the Horizon 2020 Framework Programme of the European Union under Grant Agreement nº 644906.

Partners
EXUS AE (Coordinator), ICCS, KINGSTON, CERTH, Maxeler Technologies Limited, UPPSALA UNIVERSITET, UNISR, time.lex, EUR, CHS, LOBA, PAGNI, GNUBILA FRANCE, NTU

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

Currently, a researcher may obtain health-related data for the processing of which the data subject did not give a written and unequivocal consent only after the prior obtaining of an authorization from the DPA, as explained above.

Except for emergency reasons, the authorization mentioned above may be given only after consulting the Romanian College of Physicians.

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

Given the entry into force of GDPR, no prior notification is needed and consequently no authorization is to be obtained.

According to the Law no. 190[27], the processing of genetic, biometric or health-related data for the purpose of automated decision-making or profiling is permitted with the explicit consent of the data subject, or if the processing is carried out under explicit legal provisions, by establishing appropriate measures to protect the legitimate rights, freedoms and interests of the data subject. The prohibition cannot be lifted by the consent of the data subject. Moreover, the processing of health-related data for the purpose of assuring public health, as defined in Regulation no. 1338 cannot be further processed for other purposes, by third party entities.

- **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-related data for research purposes.

The setting up of and the use of a private database with health-related data for research purposes will fall under the data processing general regime set by GDPR, as of May 25, 2018.

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

According to the Law no. 190[28], the processing of genetic, biometric or health-related data for the purpose of automated decision-making or profiling is permitted with the explicit consent of the data subject, or if the processing is carried out under explicit legal provisions, by establishing appropriate measures to protect the legitimate rights, freedoms and interests of the data subject. The prohibition cannot be lifted by the consent of the data subject. Moreover, the processing of health-related data for the purpose of assuring public health, as defined in Regulation no. 1338 cannot be further processed for other purposes, by third party entities.

- **PUBLIC DATABASES**

[27] Article 3
[28] Article 3

Co-funded by the Horizon 2020 Framework Programme of the European Union under Grant Agreement nº 644906.

Partners
EXUS AE (Coordinator), ICCS, KINGSTON, CERTH, Maxeler Technologies Limited, UPPSALA UNIVERSITET, UNISR, time.lex, EUR, CHS, LOBA, PAGNI, GNUBILA FRANCE, NTU

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

Order no. 1123/849/2016 for the Approval of the Data, Information and Operational Procedures Required to Use and Operate the Patient's Electronic Health Record (DES) provides that the patient will be able to see who has accessed his/her electronic file, as well as the time, the day and computer IP that has been used. He/she will also be able to grant or withdraw doctors' access to the data in their electronic file.

The healthcare providers who are not in a contractual relationship with health insurance houses and doctors working legally with them, in order to use the DES system are required to be enrolled in the health insurance information platform.

In order to enroll in the health insurance information system, healthcare providers will submit to the headquarters of the health insurer within the administrative-territorial area where they operate an application for the use of a qualified certificate in the computer health insurance platform.

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

The current existing procedures and rules will be entirely repealed by GDPR.

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 Leukemia (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 generalized to other healthcare disease models". [29]

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 GDPR.

1. Type 2 diabetes

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

The operations performed in the AEGLE project qualify as processing for research in the field of health purposes, and this is why the prior filing of a notification with the DPA and the obtaining of an authorization is currently requested.

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

Co-funded by the Horizon 2020 Framework Programme of the European Union under Grant Agreement nº 644906.

Partners
EXUS AE (Coordinator), ICCS, KINGSTON, CERTH, Maxeler Technologies Limited, UPPSALA UNIVERSITET, UNISR, time.lex, EUR, CHS, LOBA, PAGNI, GNUBILA FRANCE, NTU

Once GDPR has been implemented, the provisions of GDPR will be applicable. In any case, the data subjects must be informed of the transfer of their data in accordance with GDPR provisions.

2. Intensive Care Unit (ICU)

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

The operation performed in the AEGLE project qualifies as processing for research in the field of health-related purposes, and this is why the prior filing of a notification with the DPA and the obtaining of an authorization is currently requested.

Once GDPR has been implemented, the provisions of GDPR will be applicable. In any case, the data subjects must be informed of the transfer of their data in accordance with GDPR provisions.

The data are collected by health professionals in ICU services when they are treating patients. The processing of such data for research in the field of health assumes a compatible purpose. It is possible for health professionals to transfer the data they have collected to research; however, the recipient will be obliged to follow professional secrecy. Additionally, the data subjects will have to be informed about the transfer, and they may oppose it.

3. Chronic Lymphocytic Leukaemia (CLL)

The AEGLE project re-uses, after pseudonymization, 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 operation performed in the AEGLE project qualifies as processing for research in the field of health-related purposes, and this is why the prior filing of a notification with the DPA and the obtaining of an authorization is currently requested.

Once GDPR has been implemented, the provisions of GDPR will be applicable. In any case, the data subjects must be informed of the transfer of their data in accordance with GDPR provisions.

Co-funded by the Horizon 2020 Framework Programme of the European Union under Grant Agreement nº 644906.

Partners
EXUS AE (Coordinator), ICCS, KINGSTON, CERTH, Maxeler Technologies Limited, UPPSALA UNIVERSITET, UNISR, time.lex, EUR, CHS, LOBA, PAGNI, GNUBILA FRANCE, NTU