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

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in Riga, Latvia, 6 April 2018, updated 25 July 2018

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

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1. Overview of the legal framework

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

What are the relevant applicable provisions governing the processing of health data in your country? Please provide online references (in ENG), a brief description and any specific relevant information.

- *Fizisko personu datu apstrādes likums* - The Personal Data Processing Law[1]

The Personal Data Processing Law came into force on 5 July 2018. Pursuant to the GDPR, it creates the national system of personal data protection. The law establishes the institutions necessary for this purpose, defines their competence and basic principles of operation, regulates the activities of data protection specialists and states the rules of data processing and the rights of data subjects.

- *Ārstniecības likums* – the Medical Treatment Law[2]

This law defines the framework for storing of health data in the Health Information System. On the basis of this law, the Cabinet of Ministers has issued Regulations No. 134[3] 'Regulations Regarding Unified Electronic Information System of the Health Sector'. The regulations stipulate that the Health Information System ensures, including but not limited to, the processing of personal health data necessary for the provision of statistics and research.

- *Pacientu tiesību likums* – the Law on the Rights of Patients[4]

The law determines that the information relating to an identified or identifiable patient is protected in accordance with the laws governing the data protection of natural persons. Additionally, the law determines in which cases and to which persons the information about the patient is available. This law is crucial for the storage and use of patient health data. On the basis of this law, the Cabinet of Ministers has issued Regulations No. 446 'Procedures for Using the Patient Data in a Specific Research'.[5] The regulations determine the procedures by which the competent national regulatory authority authorises the use of patient data in medical records for a particular research. These regulations together with the Law On the Rights of Patients form the main legal basis for this particular questionnaire.

- *Cilvēka genoma izpētes likums* - Human Genome Research Law[6]

[1] The Personal Data Processing Law, https://likumi.lv/ta/id/300099; there is no English translation yet.
[2] Medical Treatment Law, https://likumi.lv/ta/en/id/44108-medical-treatment-law (an outdated translation is available at http://www.vvc.gov.lv/export/sites/default/docs/LRTA/Citi/Medical_Treatment_Law.pdf, with amendments until September 2014).
[3] Cabinet of Ministers Regulations No. 134, https://likumi.lv/ta/en/id/264943-regulations-regarding-unified-electronic-information-system-of-the-health-sector (an outdated translation is available at http://vvc.gov.lv/export/sites/default/docs/LRTA/MK_Noteikumi/Cab._Reg._No._134_-_United_Electronic_Information_System_of_the_Health_Sector.pdf, without amendments).
[4] Law On the Rights of Patients, https://likumi.lv/ta/en/id/203008-law-on-the-rights-of-patients (an outdated translation is available at http://vvc.gov.lv/export/sites/default/docs/LRTA/Likumi/Law_On_the_Rights_of_Patients.doc, with amendments until Septeber 2013).
[5] Cabinet Regulations No. 446, https://likumi.lv/ta/en/id/275747-procedures-for-using-the-patient-data-in-a-specific-research (available in English, except the Annexes, at http://vvc.gov.lv/image/catalog/dokumenti/Cab.%20Reg.%20No.%20446%20-%20Procedures%20for%20Using%20the%20Patient%20Data.doc).
[6] Human Genome Research Law, https://likumi.lv/doc.php?id=64093 (an outdated translation is available in English at http://www.vvc.gov.lv/export/sites/default/docs/LRTA/Likumi/Human_Genome_Research_Law.doc).

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The purpose of this law is to regulate the establishment and operation of the genome database and genetic research, to ensure the voluntary nature and confidentiality of the gene donation in respect of the identity of gene donors, as well as to protect persons from the misuse of genetic data and the discrimination related to the genetic data. On the basis of this law, the Cabinet of Ministers has issued Regulations No. 692 'On Genetic Research Procedure;[7] Regulations No. 135 'On Procedure For Creating, Supplementing and Maintaining the Register Of the Genome';[8] and Regulations No. 695 'On Provisions On the Procedure For Storing And Issuing the Samples Stored In the Genome Database'.[9]

Before the Personal Data Processing Law came into force, the Personal Data Protection Law governed the collection and processing of personal data. This law had transposed the Directive No. 9/46 on the protection of individuals with regard to the processing of personal data and on the free movement of such data.

Shared electronic health records are indirectly relevant in this context because they can potentially be an important source for health-related research. Do shared electronic patient records exist in your country? How is the sharing of electronic patient records regulated?

The Medical Treatment Law defines the framework for storing of health data in the Health Information System (Chapter XIV). On the basis of this law, the Cabinet of Ministers Regulations No. 134 have been issued – 'Regulations Regarding Unified Electronic Information System of the Health Sector'. The regulations determine the health information monitoring authority - the National Health Service - and its status and responsibilities. The regulations further clarify that the Health Information System ensures centralised processing of data related to a person's health, processing of data related to a person's health, which is required for the provision of statistics and research, writing out and circulation of the electronic prescriptions among medical practitioners and pharmacists, issuing and circulation of sick-leave certificates, electronic booking of a patient's appointment, electronic processing of referrals for the receipt of a healthcare service, electronic transmission of payment data on State funded healthcare services and other services.

The information in the Health Information System is processed by and is available to:

1) medical practitioners and medical support persons - for the purpose of medical treatment;
2) pharmacists and pharmacist assistants - for the provision of pharmaceutical care;
3) the National Health Service;
4) the Health Inspectorate – in order to ensure the supervision of the health sector;
5) the State Social Insurance Agency - for the administration of the incapacity pages issued via the health information system;
6) the State Labour Inspectorate - for the investigation and record of accidents at work and occupational diseases;

[7] Cabinet Regulations No. 692 'On Genetic Research Procedure', https://likumi.lv/doc.php?id=92330 (not available in English).
[8] Regulations No. 135 'On Procedure For Creating, Supplementing And Maintaining the Register Of the Genome', https://likumi.lv/doc.php?id=128393 (not available in English).
[9] Regulations No. 695 'On Provisions On the Procedure For Storing And Issuing the Samples Stored In the Genome Database', https://likumi.lv/ta/id/92352-noteikumi-par-genoma-datu-baze-uzglabato-kodeto-audu-paraugu-kodeto-dns-aprakstu-kodeto-veselibas-stavokla-aprakstu-un-kodeto-g (not available in English).

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7) the State Commission of Doctors of Health and Capacity for Expertise.[10]

Can data stored in these records be used for research purposes?

The Law On the Rights of Patients together with the Cabinet of Ministers Regulations No. 446 state that:

Patient records in medical records may be used in a research if one of the following criteria is met:

1) **the patient cannot be directly or indirectly identified** on the basis of the information to be analysed;

2) **the patient has agreed in writing** that information about him is used in a particular research.

Patient records in medical records may be used in the research, ***even if the above conditions are not met, if all the following conditions are met at the same time****:*

1) the research is carried out in the public interest;
2) the competent national regulatory authority has authorised the use of patient **data in the particular research in accordance with the procedures specified by the Cabinet of Ministers** (the Cabinet of Ministers Regulations No. 446);
3) the patient has not previously in writing prohibited the transfer of his data to the researcher;
4) the consent of the patient cannot be obtained by reasonable means;
5) the benefit of a research to the public health is commensurate with the limitation of the right to privacy.[11]

The authorisation for the use of patient data is issued by the Center for Disease Prevention and Control. A person who wishes to obtain the authorisation, submits an application to the aforementioned institution. The application forms and the information to be provided are provided in the Annex to the Cabinet of Ministers Regulations No. 446.

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?

Is the GDPR implemented in your country by an entirely new legislative text or via amendments to the current data protection law? Please explain.

The necessary changes to the national data protection framework were introduced via the new Personal Data Processing Law. Upon entry into force of the Personal Data Processing Law, the previous law, the Personal Data Protection Law, lost its force on 5 July 2018.

[10] Law On the Rights of Patients, Section 10 (5^1).
[11] Law On the Rights of Patients, Section 10 (7), (8).

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What are the main characteristics of the legislative implementation of the GDPR in your country?

The basic principles for processing of the personal data have remained unchanged in comparison with the previous law (the Personal Data Protection Law). Also with regard to the GDPR, the new law does not impose stricter rules on the data processing and/or access. For example, rules on the rights and obligations of controllers and processors, the procedures for the exercise of the rights of data subjects, the appointment and tasks of the data protection officer, the rules for transferring the data to third countries, the development of a certification mechanism and codes of conduct, the notification of personal data, the recording of processing operations are already included in the GDPR.

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 previous legal framework?

Already before the GDPR came into force, the data protection supervisory authority was the Data State Inspectorate (**DSI**), which is also the competent authority pursuant to the GDPR.

The main goals of the DSI were the supervision of the personal data protection, the accreditation and supervision of reliable certification service providers, the supervision of data protection in the electronic communications sector, the supervision of provision of the information society services and the supervision of credit information offices.*Therefore, its functions were:*

1) accreditation and supervision of reliable certification service providers;
2) registration of personal data processing;
3) registration of personal data protection specialists;
4) assessment of the level of protection of personal data and the provision of written consent for the transfer of personal data to countries that are not Member States of the European Union or the European Economic Area and do not ensure an adequate level of protection of personal data;
5) supervision of the Biometric Data Processing System Law;
6) collection of statistical information and transmission to the European Commission on requests from institutions for obtaining data to be retained and the issue of data to be retained;
7) dealing with the complaints and decision-making in relation to the description of the state of health and collection of genealogical data, tissue samples, DNA profile, description of the state of health and the coding and decoding of genealogical data, as well as tissue samples, DNA profiles, description of the health status and genealogical data processing;
8) supervision of personal data protection in the framework of the Schengen Information System, including the provision of representation in the supervisory institution of Latvia;

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9) supervision of the personal data protection in the framework of Europol's information system, including the provision of representation in the supervisory institution of Latvia. [12]

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

After the GDPR has come in force, the DSI still is the responsible institution for the data protection. The role of the DSI is now regulated in detail in the new Personal Data Processing Law. The new law distinguishes the tasks (according to Art. 57 of the GDPR) and rights (according to Art. 58 of the GDPR) of the DSI.

In addition to tasks stated in Art. 57 of the GDPR, ***the DSI fulfils the following tasks***:

1) supervises the conformity of data processing with the requirements of law, including the cases when the controller is forbidden by law to provide information to the data subject and has received an appropriate application from the data subject;

2) promotes the effectiveness of data protection;

3) ensures the data protection certification procedure;

4) ensures the qualification of data protection specialists and maintains a list of data protection specialists who have passed the qualification exam;

5) in accordance with its competence, makes recommendations to the Saeima (Parliament of Latvia), the Cabinet of Ministers, local governments (municipalities) and other institutions regarding the need to issue or amend the legislation, as well as participates in drafting of the laws and development planning documents and gives opinions on draft laws and development planning documents drafted by other institutions;

6) provides opinions on the compliance of data processing systems created in state administration institutions with the requirements of law;

7) provides an opinion to the national accreditation body on the compliance of the certification body with the requirements of Art. 43(2) of the GDPR and the inspection requirements and criteria set out in Art. 43(3) of the GDPR;

8) cooperates with the supervisory authorities of foreign data protection, information disclosure and access control and prohibition of sending commercial communications;

9) ensures that the data subject's request for information of themselves is transmitted to the European Judicial Cooperation Unit (Eurojust) and the European Police Office (Europol);

10) represents the Republic of Latvia in international organisations and activities in the field of data protection;

[12] Functions of the Data State Inspectorate, http://www.dvi.gov.lv/en/inspectorate/functions/.

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11) carries out research, analyses the situation, makes recommendations and opinions as well as informs the society about topical issues in areas of its competence;

12) performs other tasks stated in law.

In addition to rights stated in Art. 58 of the GDPR, ***the DSI is entitled to perform the following***:

1) to perform the data processing verification (hereinafter - verification) in order to determine the conformity of data processing with the requirements of law;

2) to draw up administrative violations' protocols, to investigate administrative violation cases and to impose administrative penalties for violations which are in its competence;

3) within the scope of its competence, to request and receive without charge, in the amount and form prescribed, information, documents or their copies, and other materials, including the information of restricted accessibility, from private persons, state administration institutions and officials;

4) to visit state administration institutions and production facilities, warehouses, commercial and other non-residential premises that are located in the territory of Latvia, and are owned or used by legal and natural persons, in order to verify, within the scope of their competence, the compliance of the managerial activities with the requirements of law;

5) within the scope of its competence, to freely familiarize itself with and access all types of information contained in the registers, information systems and databases (regardless of the identity of the information) in order to obtain information necessary for the verification;

6) within the scope of its competence, to request and receive information, documents and other materials about services rendered to persons that are necessary for the verification;

7) to request and receive an independent and objective expert opinion within the framework of the verification;

8) to provide answers in English, when co-operating with other supervisory authorities and dealing with non-resident complaints;

9) to submit an action for violation of the Personal Data Processing Law or the GDPR to the court.

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?

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

a. Transposition of Article 8.4 of Directive 95/46

While the Directive 95/46 was still in force, the legislator of Latvia did not insert any additional exemptions for the processing of health data for research purposes. As mentioned before, the Law on the Rights of Patients states the following:

*Patient records in **medical records may be used** in a research if one of the following criteria is met*:

1) the patient cannot be directly or indirectly identified on the basis of the information to be analysed;
2) the patient has agreed in writing that information about him is used in a particular research.

Patient records recorded in medical records may be used in the research, even if the above conditions are not met, if all the following conditions are met at the same time:

1) the research is carried out in the public interest;
2) the competent national regulatory authority has authorised the use of patient data in a particular research in accordance with the procedures specified by the Cabinet of Ministers;
3) the patient in writing has not previously prohibited the transfer of his data to the researcher;
4) the consent of the patient cannot be obtained with reasonable means;
5) the benefit of a research to public health is commensurate with the limitation of the right to privacy.

Also currently there are no new exemptions, as Chapter VIII of the new Personal Data Processing Law determines the same what is set out in GDPR, and the Law on the Rights of Patients has not been amended.

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? What is the scope?

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Yes. The Regulations No. 446 issued by the Cabinet of Ministers – 'Procedures for Using the Patient Data in a Specific Research' – state the procedure by which the competent national regulatory authority authorises the use of patient data in medical records for a particular research.[13]

Which are the steps, and who are the key actors?

The Center for Disease Control and Prevention issues an authorisation for the use of patient data in the medical records for a specific research.

A person who wishes to receive an authorisation **submits an application to the Center for Disease Control and Prevention** (*see Annex 1 to the Regulations No. 446*). *The application must be accompanied with the following documents:*

1) CVs of the research leader and leading researchers in accordance with the template provided in Annex 2 to the Regulations;

2) copies of educational documents of the research director and leading researchers;

3) research protocol - a theoretical description of the methodological preconditions.

The Center for Disease Control and Prevention issues the authorisation *if all the following conditions are met at the same time:*

1) the use of the patient's data for the purpose is necessary for the achievement of the research objectives and is proportionate;

2) the objectives of the research cannot be achieved by using unidentifiable patient data in different databases and registers;

3) it is planned to publish the results of the planned research;

4) the person has registered the processing of the patient data for a particular purpose or has appointed a personal data protection specialist who is registered with the DSI;

5) the research leader and leading researcher are qualified to successfully complete the research.

The Center for Disease Control and Prevention publishes information online on the issued authorisations within five working days after taking the decision, specifying:

1) the name of the person, if the recipient is a natural person, or the name and registration number if the recipient is a legal person;

2) the title of the research;

3) **the list of medical institutions from which it is intended to request the medical documentation necessary for the research**;

4) the period for which the authorisation is issued.

[13] Cabinet of Ministers Regulations No. 446, 'Procedures For Using the Patient Data In a Specific Research', https://likumi.lv/ta/en/id/275747-procedures-for-using-the-patient-data-in-a-specific-research.

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

All the aforementioned laws apply to the activities of researchers which are done in accordance to the authorisation provided, taking into account that the issuance of an authorisation is an exception from the general procedure (*the provisions stated in the Medical Treatment Law and the Law On the Rights of Patients*). The researchers with the issued authorisation must carry out research activities within the limits of the authorisation in accordance with the instructions of the Center for Disease Control and Prevention.

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

No. Only the conditions described under Section 2 B of this Report regarding the purpose of the data processing apply.

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

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?

There are no specific provisions. Only the conditions described under Section 2 A of this Report regarding the purpose of the data processing apply. The Law On the Rights of Patients stipulates that information about the patient may only be disclosed with a written consent of the patient or if the patient cannot be directly or indirectly identified on the basis of the information to be analysed.

Information relating to an identified or identifiable patient must not be disclosed even after the patient's death. **However, the law states that there are exceptions on disclosure of information to the patient's spouse, children, parents, patient's brother or sister, grandparents and grandchildren**. Information about a patient after his death *can be disclosed to aforementioned persons if:*

1) the information can affect the lives or health of these individuals or facilitate the provision of healthcare services to them;

2) the information is related to the patient's death or medical treatment before his death.[14]

The minor's legal representative has the right to be informed about the state of health of the patient who is a minor. The minor patient's legal representative is not provided with information if the disclosure of such may harm the interests of the patient. The decision taken by the physician is recorded in the patient's medical records and the physician informs the Orphan's Court thereof.

[14] Law On the Rights of Patients, Section 7, Section 10 (3), (4).

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In order to ensure the rights and interests of a minor, in cases when there is a justified need but it is impossible to find out information about the health of the minor through the parents or other legal representatives or from the minor itself, the following persons have the right to receive contact information on the minor's family doctor or paediatrician: the State Police, the Municipal Police, the State Children's Rights Protection Inspectorate, the State Probation Service, the Orphan's Court, the social service, the physicians of the social correction educational institution and the place of imprisonment for performing their duties prescribed in laws.[15]

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

There are none.

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?

No, there are no specific penalties if the conditions for processing for scientific research in the field of health purposes are not respected.

Taking into account that the DSI is the supervisory institution of personal data protection, in accordance with the Personal Data Protection Law it is competent to impose administrative penalties for violations in the processing of personal data in accordance with the procedure prescribed by law.

The fines under the Latvia Administrative Violations Code amount up to EUR 700 for natural persons, up to EUR 700 for officials, and up to EUR 14 000 for legal persons, with or without confiscation of objects and tools used in committing the offence. However, as the maximal penalties are set in the Article 83 of the GDPR, the fines stated in the Latvia Administrative Violations Code will not be applied to natural persons to their maximal amounts. Also, in accordance with the GDPR, if the fine creates a disproportionate burden on a natural person, DSI has the right to issue a reprimand instead of a fine.

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

Was 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? Where in the applicable legislation can it be found?

No, before the GDPR came into force, there was no specific regime. The regulation was stipulated the Personal Data Protection Law, Sections 2, 8, 9 and 10.

[15] Law On the Rights of Patients, Section 10 (6), (10).

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What were this regime's main steps and conditions?

The aforementioned Sections 2, 8, 9 and 10 provided the definitions of the controller, its rights and obligations regarding the storage and processing of the personal data.

(Section 2) **Controller** - a natural or legal person, a state or local government institution which, alone or with others, determines the purposes and processing of personal data processing and **is responsible for the processing of personal data** in accordance with the Personal Data Protection Law.

(Section 8) When acquiring personal data from a data subject, **the controller is required to provide the data subject with the following information**, unless it is already available to the data subject:

1) the controller's name (if the controller is a legal entity) or given name, surname and address;
2) the intended purpose of processing personal data.

At the request of the data subject, the controller is also required to provide the following information:

1) potential recipients of the personal data;
2) the rights of the data subject to access and make corrections to his personal data;
3) whether the response is compulsory or voluntary, as well as the possible consequences of failure to reply;
4) the legal basis for processing of the personal data.

(Section 9) If the personal data is not obtained from the data subject, **the controller is obliged to provide the data subject with the following information** when collecting or disclosing such personal data to third persons for the first time:

1) the controller's name (if the controller is a legal entity) or given name, surname and address;
2) the intended purpose of processing the personal data.

The above *(Section 9)* did not apply if:

1) the processing of the personal data is provided for in another law;
2) when processing personal data for scientific, historical or statistical researches, for the establishment of the national documentary heritage or provision of official publication, the informing of the data subject requires **inordinate effort or is impossible.**

(Section 10) **In order to protect the interests of the data subject**, the controller ensures:

1) the processing of personal data takes place with integrity and is carried out lawfully;
2) the personal data is processed only in conformity with the intended purpose and to the extent required;
3) the personal data is stored so that the data subject is identifiable during a relevant period of time, which does not exceed the time period prescribed for the intended purpose of the data processing;

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4) the personal data is accurate and that it is updated, rectified or erased in a timely manner if such personal data is incomplete or inaccurate in accordance with the purpose of the personal data processing.

The processing of personal data for purposes other than those originally intended was permissible if it did not violate the rights of the data subject **and was carried out for the purposes of scientific or statistical research** only in accordance with the conditions specified in Sections 9 and 10 (see above).

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

How was the notion of further processing regulated in your national framework before the GDPR?

The concept of notion of further processing was not regulated, but the Personal Data Protection Law determined the rights and obligations of the data subject and the controller at the time the data is processed or when the data is in authority of the controller.

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

Conditions like these were not specifically provided.

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

Considering that the concept of notion of further processing of data was not regulated, but the law determined rights of the data subject, Chapter III of the Personal Data Protection Law stipulated **the rights and obligations of data subjects.**

In accordance to this regulation, the data subject had full discretion regarding his data stored in any data processing system - to get the data from the controller (persons, institutions etc.), to prohibit processing of personal data, to request correction and destroying of their personal data, and to determine which data is stored. However, the data subject was not entitled to receive the information referred above if it was prohibited to disclose this information in accordance with the law in the field of national security, State protection, public security, criminal law, as well as with a view to ensure the State financial interests in the tax affairs or supervision of participants of the financial market and macroeconomic analysis.[16]

The data subject had the right to submit a complaint to the DSI if the controller did not comply with its statutory obligations.

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

The data subject's rights in process for scientific research purposes were not specifically regulated, it was presumed that the rights described in Section 3 of this Report apply.

[16] Personal Data Protection Law, https://likumi.lv/ta/id/4042-fizisko-personu-datu-aizsardzibas-likums.

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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 new Personal Data Processing Law has come into force on 5 July 2018 and it mainly stipulates what is included in GDPR (Chapter II of the GDPR). Namely, Section 25 (3) of the law determines that data processing complies with the data processing principles set out in Article 5 of the GDPR, including those that determine that data can be obtained for specific, clear and legitimate purposes and only to the extent that is necessary for the purpose of data processing purposes. Data processing for purposes other than the purpose for which the data was initially obtained is allowed if such data processing is not prohibited and is one of the bases for data processing specified in the GDPR, or data processing is compatible with the original purpose of the GDPR. Also the data subjects have the rights stated in the GDPR.

Thus, there is no specific regime applying to processing for research in the field of health.

Regarding the use of data for the research the Personal Data Processing Law provides the following:

1) where data is processed for statistical purposes, the rights of the data subject, as provided for in Articles 15, 16, 18 and 21 of the GDPR, do not apply in so far as they may prevent or significantly impede the achievement of the specific purpose and the derogations are necessary for the attainment of those purpose;

2) where the data is processed for archival purposes in the public interest in order to create, accumulate, evaluate, preserve and use the national documentary heritage, the rights specified in Articles 15 and 16 of the GDPR can be exercised by the data subject in accordance with the laws governing the archives, while the rights of the data subject specified in Articles 18, 19, 20 and 21 of the GDPR do not apply in so far as they may preclude or significantly impede the achievement of the specific purpose, and the derogations are necessary to achieve these purpose;

3) where the data is processed for the purposes of scientific or historical research in the public interest, the rights of the data subject, as provided for in Articles 15, 16, 18 and 21 of the GDPR, do not apply in so far as they may prevent or significantly impede the achievement of the specific purpose and the derogations are necessary in order to achieve those purposes.

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

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

Article 9 (4) of the GDPR imposes a discretion on the part of the Member State as to whether to maintain or introduce additional conditions, including restrictions on the processing of genetic data, biometric data or health data. Recital 52 states that the derogation from the prohibition on processing specific categories of personal data should also be allowed if it is provided for by EU or national law and provided that adequate safeguards are in place to protect personal data and other fundamental rights where this is in the public interest, in particular the processing of personal data in the field of employment legislation, social protection legislation, including pensions and health security, surveillance and warning, prevention or control of contagious infectious diseases and other serious health threats. Such a derogation may be made for health-related purposes, including for the management of public health and healthcare services, in particular to ensure the quality and cost-effectiveness of procedures used to claim benefits and health insurance schemes, or to archive in the public interest, for scientific or historical research purposes; or for statistical purposes.

The Annotation of the Personal Data Processing Law states that, if in the field of insurance there is recognized the need to introduce additional conditions for the processing of genetic data, biometric data or health data, and if it is in the public interest, such regulations will need to be incorporated into the laws of the sector, providing appropriate guarantees for the protection of personal data and other fundamental rights. Such regulatory act will need to include specific provisions regarding the purposes for which the processing is carried out, the categories of processing, the categories of personal data, the scope of the conditions imposed, the guarantees for preventing the misuse or unlawful access or transmission of the data, storage periods and applicable guarantees and other information, taking into account the nature, scope and purpose or the categories of the processing, as well as the risks to the rights and freedoms of the data subjects.

Currently there is no information or indication if and how the existing procedures and rules will change and also have been no changes yet apart from the aforementioned Personal Data Processing Law.

5. Further processing for research purposes under the GDPR

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

The Personal Data Processing Law only clarifies the way the GDPR is applied in Latvia and does not specifically mention further processing. Thus, the basic principles of personal data processing remain unchanged and the GDPR substantially extends the rights of the data subject.

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6. Health data sources for research purposes

a. Sources of data and their regulation

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

- **DIRECT COLLECTION FROM PATIENTS:**

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

This procedure still is governed by the aforementioned Law On the Rights of Patients (Sections 10 (7), (8), (9))and the Cabinet of Ministers Regulations No. 446 – 'Procedures For Using the Patient Data In a Specific Research'.

Patient records in medical records can be used in a research if the patient has agreed in writing that information about him is used in a particular research.

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

Currently there is no information or indication if the currently existing procedures and rules will change. However, the principles set in the GDPR and the Personal Data Processing Law must be strictly observed.

- **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.

The main normative act regulating the use of data in studies is the Law On the Rights of Patients (Sections 10 (7), (8), (9)).

Patient records in **medical records may be used in a research** under one of the following conditions:

1) the patient cannot be directly or indirectly identified on the basis of the information to be analysed;

2) the patient has agreed in writing that information about him is used in a particular research.

Patient records in medical records may be used in a research, **also without observing the conditions specified before**, by providing that the following conditions exist simultaneously:

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1) the research is carried out in the public interest;

2) the competent national regulatory authority has authorised the use of patient data in a particular research in accordance with the procedures specified by the Cabinet of Ministers;

3) the patient in writing has not previously prohibited the transfer of his data to the researcher;

4) the consent of the patient cannot be obtained with reasonable means;

5) the benefit of a research to public health is commensurate with the limitation of the right to privacy.

The second normative act is Cabinet of Ministers Regulations No. 446 – 'Procedures for Using the Patient Data In a Specific Research'. Pursuant to these regulations a person who wishes to receive an authorisation submits an application to the Center for Disease Prevention and Control (Annex 1 to the regulations). **The application must be accompanied by the following documents:**

1) CVs of the research leader and leading researchers in accordance with the template provided in Annex 2 to the Regulations;

2) copies of educational documents of the research director and leading researchers;

3) research protocol – a theoretical description of the methodological preconditions.

The Center for Disease Prevention and Control issues the authorisation if all the following conditions are met at the same time:

1) the use of the patient's data for the purpose is necessary for the achievement of the research objectives and is proportionate;

2) **the objectives of the research cannot be achieved by using unidentifiable patient data from different databases and registers**;

3) it is planned to publish the results of the planned research;

4) the person has registered the processing of the patient data for a specific purpose or has appointed a personal data protection specialist who is registered with the DSI;

5) the research leader and leading researcher are qualified to successfully complete the research.

It is equally important to mention that the **processing of health data related to genetic research** in Latvia is governed by the Human Genome Research Law.[17] According to this law a **Genome database** has been established and the Cabinet of Ministers has issued regulations (Regulations No. 692 'On Genetic Research Procedure'; not available in English)[18] regarding the maintenance of this database (Regulations No. 135 'On Procedure For Creating, Supplementing And Maintaining the Register Of the Genome'; not available in English).[19]

Access to the data in this database is allowed to public medical institutions and gene researchers. Genetic research is allowed only for studying human genes for the purpose to detect disease diagnostic and treatment methods that

[17] Human Genome Research Law, https://likumi.lv/doc.php?id=64093.
[18] Cabinet Regulations No. 692 'On Genetic Research Procedure', https://likumi.lv/doc.php?id=92330 (not available in English).
[19] Regulations No. 135 'On Procedure For Creating, Supplementing And Maintaining the Register Of the Genome', https://likumi.lv/doc.php?id=128393 (not available in English).

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will help to assess the health of individuals and prevent the occurrence of diseases. Data accumulation in the database is possible only if the data subject has given his consent.

Further on access to the gene database (for gene researchers).

The Provisions on the procedure for storing **and issuing** the samples stored in the genome database are governed by Cabinet Regulations No. 695.[20] The genetic data from the database is issued upon submitting an application (a sample is provided in the Appendix to the Regulations No. 695). The Requested data is provided by the database controller.

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

There is currently no information or indication if the currently existing procedures and rules will change.

- **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 Latvian laws do not specifically regulate this issue.

I. PUBLIC DATABASES

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

This procedure is regulated by the aforementioned normative acts (the Law On the Rights of Patients (Sections 10 (7), (8), (9) and Cabinet of Ministers Regulations No. 446 'Procedures For Using the Patient Data In a Specific Research') as explained 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?

There is currently no information or indication if the currently existing procedures and rules will change.

[20] Provisions on the procedure for storing and issuing the samples stored in the genome database are stipulated in Cabinet Regulations No. 695, https://likumi.lv/ta/id/92352-noteikumi-par-genoma-datu-baze-uzglabato-kodeto-audu-paraugu-kodeto-dns-aprakstu-kodeto-veselibas-stavokla-aprakstu-un-kodeto-g (not available in English).

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b. The application of the national framework to the AEGLE cases

1. Type 2 diabetes; Intensive Care Unit (ICU); Chronic Lymphocytic Leukaemia (CLL).

The AEGLE project uses, after pseudonymisation, existing databases with health data collected from patients who have 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, and this is why the Law On the Rights of Patients (Sections 10 (7), (8), (9)) and Cabinet of Ministers Regulations No. 446 'Procedures For Using the Patient Data In a Specific Research' apply.

Once the data source has granted permission to the medical data, before the start of any processing operation, the medical treatment institution will implement a note in the medical documents of the patient. The note must include information on medical institutions from which the medical information necessary for the research can be requested. If the data is collected by health professionals in the Health Information System, then these health professionals may transfer the data to researchers.

Once the GDPR has been implemented:

Currently there is no information or indication if the currently existing procedures and rules will change.

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