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LATVIA

‘Big data’ analytics and the processing of health data for scientific research purposes:

The Latvian legal framework

The rules applicable to data protection are in the midst of change throughout Europe with the implementation of the **General Data Protection Regulation.**

A legal assessment was prepared for the AEGLE platform based on country reports comparing the situation under the previous regime and the GDPR, while applying the new rules specifically to the AEGLE platform.

While these country report are primarily focused on framework applicable to the AEGLE Platform, they will prove a valuable source of information to anyone interested in learning more about on the data protection aspect of scientific research in the field of health care and the changes it is undergoing.

Research Protocol by Valts Nerets, SORAINEN
in Riga, Latvia, 6 April 2018

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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 till 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 Protection Law[1] (the law is in force at the moment but will be replaced upon the entry into force of the Personal Data Processing Law. Currently the law is in the form of a draft law and is under consideration of the Parliament. It is expected that the Personal Data Processing Law will come into force as of 25 May 2018. It is not yet available in English).

The Personal Data Protection Law governs the collection and processing of personal data. The law transposes the Directive No. 95/46 on the protection of individuals with regard to the processing of personal data and on the free movement of such data.[2]

- *Ārstniecības likums* – the Medical Treatment Law[3]

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[4] '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[5]

The law determines that information relating to an identified or identifiable patient is protected in accordance with the laws governing the data protection of natural persons. Also the law determines in which cases and to which

[1] Personal Data Protection Law, https://likumi.lv/ta/en/id/4042-personal-data-protection-law (available in English at www.vvc.gov.lv/export/sites/default/.../Personal_Data_Protection.doc).

[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] 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).

[4] 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).

[5] 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).

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persons 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'.[6] 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[7]

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;[8] Regulations No. 135 'On Procedure For Creating, Supplementing and Maintaining the Register Of the Genome';[9] and Regulations No. 695 'On Provisions On the Procedure For Storing And Issuing the Samples Stored In the Genome Database'.[10]

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 what information the Health Information System provides – data related to personal health, which is necessary for treatment; data processing required for the provision of statistics and research; prescribing and circulation of electronic prescriptions among medical practitioners and pharmacists; issuing of incapacitation pages; booking an electronic patient visit to a medical practitioner; personal health related data for vaccination planning, and more.

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;

[6] 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).

[7] 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).

[8] Cabinet Regulations No. 692 'On Genetic Research Procedure', https://likumi.lv/doc.php?id=92330 (not available in English).

[9] 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).

[10] 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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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 Labor Inspectorate - for the investigation and record of accidents at work and occupational diseases;

7) the State Commission of Doctors of Health and Capacity for Expertise.[11]

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 can not 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 in writing has previously not prohibited the transfer of his data to the researcher;

4) the consent of the patient can not 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.[12]

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.

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

[12] Law On the Rights of Patients, Article 10 (7), (8).

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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 will be introduced via a new legislative text - the Personal Data Processing Law. This normative act is in the form of a draft law and currently is under consideration in the parliament. Upon entry into force of the Personal Data Processing Law, the Personal Data Protection Law will lose its force.

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

What is your own assessment of the legislative approach adopted in your country for implementing the GDPR.

The basic principles for processing of the personal data, compared to the law currently in force (the Personal Data Protection Law), remain unchanged. 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 current legal framework?

The data protection supervisory authority is the Data State Inspectorate (**DSI**, authority which is also the competent authority pursuant to the GDPR).

The main purpose of the DSI is supervision of the personal data protection, the accreditation and supervision of reliable certification service providers, supervision of data protection in the electronic communications sector, and supervision of provision of the information society services and supervision of credit information offices.

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Currently the functions of the DSI are:

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;
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. [13]

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

The new law will stipulate that the DSI has the competence specified in Article 55 of the GDPR, **as well as that the DSI**:

1) monitors the compliance of data processing with the requirements of regulatory enactments;
2) promotes more effective compliance with data protection;
3) accredits the supervisory bodies of the certification body and the code of conduct;
4) provides data protection certification procedure;
5) ensures the qualification of data protection specialists.

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

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According to the draft law, tasks of the DSI in addition to those stipulated under Article 57 of the GDPR are, among others:

1) maintaining a list of the data protection professionals who have passed the qualification exam;
2) cooperating with the foreign data and other supervisory authorities;
3) cooperating with the supervisory authorities of the European Union in the implementation of this draft law and the GDPR;
4) representing the Republic of Latvia in international organisations and activities in the field of data protection.

2. Transposition of Article 8.4 of Directive 95/46

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

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

a. Transposition of Article 8.4 of Directive 95/46

The 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 can not 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;

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

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

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?

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.[14]

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 can not be achieved by using unidentifiable patient data in different databases and registers;

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

[14] 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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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.

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

All the aforementioned provisions of the laws apply to the activities of researchers according 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

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only be disclosed with a written consent of the patient or if the patient can not 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.[15]

- **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.

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 pediatrician: 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 regulatory enactments.[16]

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

There is 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.

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

[16] Law On the Rights of Patients, Article 10 (6), (10).

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

This sector is relevant if the regime applying to processing for research in the field of health is a specific regime. But it may not always apply, and in such an instance the processing is ruled by the general regime.
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?
Where in the applicable legislation can it be found?

No, there is no specific regime. The regulation is stipulated in the general law regarding the protection of personal data – the Personal Data Protection Law, Articles 2, 8, 9 and 10.

What are this regime's main steps and conditions?

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

(Article 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.

(Article 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;

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4) the legal basis for processing of the personal data.

(Article 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 *(Article 9)* does 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.**

(Article 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;

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 is permissible if it does not violate the rights of the data subject **and is carried out for the purposes of scientific or statistical research** only in accordance with the conditions specified in Article 9 and Article 10 (see above).

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

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

The concept of notion of further processing is not regulated, but the law (the *Personal Data Protection Law*) determines 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?

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Conditions like these are not specifically provided.

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

Taking into account the aforementioned that the concept of notion of further processing of data is not regulated, but the law determines rights of the data subject, Chapter III of the Personal Data Protection Law stipulates **the rights and obligations of data subjects.**

In general, the data subject has 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 ther personal data, and to determine which data is stored. However, the data subject is not entitled to receive the information referred above if it is 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.[17]

The data subject has the right to submit a complaint to the DSI if the controller does 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 are not specifically regulated, it is presumed that the rights described in Section 3 of this report apply.

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 main provisions are stipulated in Articles 41, 42 and 43 of the Personal Data Processing Law (the draft law).

The Personal Data Processing Law (draft law) in respect of the data processing for statistical, archiving, scientific or historical research purposes provides that, when data is processed for aforementioned purposes, the rights specified in Articles 15 and 16 of GDPR are exercised by the data subject in accordance with regulatory enactments in the corresponding field (field of statistics, archive, science and research respectively).

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

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However, if the data is processed for the aforementioned purposes in the public interest, **the rights of the data subject stipulated in Articles 18, 19, 20 and 21 of GDPR do not apply** to the extent that such rights may prohibit or may substantially interfere with the achievement of specific purposes, and derogations are necessary for achievement of such purposes.

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

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

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.

In view of this, in the field of insurance, 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, is to be incorporated into the regulatory enactments of the sector, providing appropriate guarantees for the protection of personal data and other fundamental rights. The regulatory act introducing additional conditions for the processing of genetic data, biometric data or health data must include specific provisions, where appropriate, for at least the purposes for which the processing is carried out or the categories of processing, the categories of personal data, the scope of the conditions imposed, the guarantees to prevent misuse or unlawful access or transmission, the definition of managerial or managerial categories, storage periods and applicable guarantees, taking into account the nature, scope and purpose of the processing or processing categories, risks to the rights and freedoms of the data subjects.

Currently there is no information or indication in respect of which sector the existing procedures and rules will change.

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?

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Currently there is no information or indication if the currently existing procedures and rules will change. The Personal Data Processing Law will only clarify the way the GDPR is applied in Latvia. As the basic principles of personal data processing remain unchanged, but the GDPR will substantially extend the rights of the data subject this is an appropriate time for each institution and company to assess whether the processing of personal data complies with the fundamental principles of personal data protection and to make all possible improvements to ensure adequate protection of personal data.

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 is regulated by the aforementioned normative acts (the Law On the Rights of Patients (Article 10, (7), (8), (9) and 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.

- **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 (Articles 10, (7), (8), (9)).

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

1) the patient can not 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.

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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:

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 can not 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 can not 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 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.[18] 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

[18] Human Genome Research Law, https://likumi.lv/doc.php?id=64093.

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English)[19] 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).[20]

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 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 reguleted in Cabinet Regulations No. 695.[21] 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.

- **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 (Article 10, (7), (8), (9) and Cabinet of Ministers Regulations No. 446 'Procedures For Using the Patient Data In a Specific 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?

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

[19] Cabinet Regulations No. 692 'On Genetic Research Procedure', https://likumi.lv/doc.php?id=92330 (not available in English).

[20] 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).

[21] Provisions on the procedure for storing and issuing the samples stored in the genome database are reguleted 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 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 (Article 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 it is allowed to request the medical information necessary for the research. 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:

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

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AEGLE

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