AEGLE

An Analytics Framework for Integrated and Personalized Healthcare Services in Europe

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AEGLE in your country

How does your country process health data after GDPR?

Lithuania

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

The Lithuanian 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 Sidas Sokolovas for SORAINEN
in Vilnius, Lithuania , *05 April 2018*

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1. Overview of the legal framework

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

a. The legislative and regulatory instruments regulating the processing of health data for research purposes (current regime)

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

The Law of the Republic of Lithuania on Legal Protection of Personal Data (hereinafter – the **Data Protection Law**) is the main law regulating data protection matters in Lithuania. The Data Protection Law implemented 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.[1]

The Law of the Republic of Lithuania on Ethics of Biomedical Research (hereinafter – the **Biomedical Research Law**) sets forth ethical requirements for biomedical research, terms and conditions of processing of human biological samples and managing personal health information for the purposes of biomedical research and activities of biobanks, terms and conditions of issuance of approvals to conduct biomedical research and supervision of conducting of biomedical research. The Biomedical Research Law implemented Directive 2001/20/EC of the European Parliament and of the Council of 4 April 2001 on the approximation of the laws, regulations and administrative provisions of the Member States relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use[2].

[1] Lithuanian: https://e-seimas.lrs.lt/portal/legalAct/lt/TAD/TAIS.29193/tZmHKefvAp?positionInSearchResults=0&searchModelUUID=13b16d0b-c016-4535-a48d-2b588400c285; English: https://e-seimas.lrs.lt/portal/legalAct/lt/TAD/ef70b5d2f14811e78f3dc265493430ae?jfwid=dg8d2q57o

[2] Lithuanian: https://e-seimas.lrs.lt/portal/legalAct/lt/TAD/TAIS.101629/zeDHkkWeJM?positionInSearchResults=1&searchModelUUID=42ee2b2c-27d8-4240-9c3a-a3bc9f96cdda; English: https://e-seimas.lrs.lt/portal/legalAct/lt/TAD/76582f93e9c811e59b76f36d7fa634f8?jfwid=-fa58gsxkq

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Other, situationally relevant laws include the Law of the Republic of Lithuania on Rights of Patients and Compensation of Damage to their Health[3] (hereinafter – the **Patients' Rights Law**); the Law on Health System of the Republic of Lithuania[4]; the Civil Code of the Republic of Lithuania[5] and various sub-statutory legal acts.

Please note that English translations may be outdated.

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

The Ministry of Health is the main managing authority of the electronic health system in Lithuania, the main implementation device of which is the State Electronic Health Services and Cooperation Infrastructure Information System (hereinafter – **ESPBI IS**). ESPBI IS is regulated by the Law of the Republic of Lithuania on Health System (Article 13[1] provides legal basis for development of ESPBI IS by introducing concept of eHealth and ESPBI IS), Order No 1057 of the Government of the Republic of Lithuania Regarding Approval of the Regulations of the State Electronic Health Services and Cooperation Infrastructure Information System[6], Order No V-657 of the Minister of Health Regarding Approval of the Operation of the State Electronic Health Services and Cooperation Infrastructure Information System[7] and other legal acts.

ESPBI IS is comprised of several databases: patients database, electronic health history database, medical devices database, ePrescription database, reports and statistics database etc.

Patients database and electronic health history databases are the most relevant with respect to this study. These databases include general patients' data (identification number, name, family status, date of birth, sex, address etc.) and special data (height, weight, body mass index, data on allergies, diagnoses and other sensitive health data) respectively.

Personal data stored and processed in the ESPBI IS is confidential and may only be provided to third parties on the basis of data transfer agreement concluded between the controller of ESPBI IS data and the recipient of this data and if the recipient is authorised to receive personal data.

Based on the fact that personal health data processed in the ESPBI IS has been collected for purposes incompatible with further processing for scientific research purposes, data in these records could be used for research purposes on the basis of data subject's consent or if specific exemptions are applicable, as provided further in this questionnaire.

[3] Lithuanian: https://e-seimas.lrs.lt/portal/legalAct/lt/TAD/TAIS.31932/wgBWAtdugU?positionInSearchResults=0&searchModelUUID=ae3f6861-dbff-4071-a65c-10066a597199; English: https://e-seimas.lrs.lt/portal/legalAct/lt/TAD/TAIS.42491?jfwid=dg8d2q5ef;

[4] Lithuanian: https://e-seimas.lrs.lt/portal/legalAct/lt/TAD/TAIS.5905/vquxCJSFbC; English: https://e-seimas.lrs.lt/portal/legalAct/lt/TAD/TAIS.23358?jfwid=dg8d2q5ff

[5] Lithuanian: https://e-seimas.lrs.lt/portal/legalAct/lt/TAD/TAIS.107687/UmloDCyzsQ?positionInSearchResults=0&searchModelUUID=c5387164-56ad-44f2-b7c2-526beaa3a57a; English: https://e-seimas.lrs.lt/portal/legalAct/lt/TAD/TAIS.404614?jfwid=dg8d2q5hg

[6] https://e-seimas.lrs.lt/portal/legalAct/lt/TAD/TAIS.406145/SXdbaAONuH

[7] https://e-seimas.lrs.lt/portal/legalAct/lt/TAD/49e35880064e11e5b0d3e1beb7dd5516/iajMaLPXPU

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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 GDPR is implemented by amending the current Data Protection Law, however the amendments essentially replace the current Data Protection Law in its entirety, abolishing currently applicable provisions and introducing new ones. The most recent version of the amending draft amendment to the Law on Legal Protection of Personal Data has been registered on 15 February 2018 (hereinafter – the **Draft Law**).

We were unable to identify GDPR related amendments of any other relevant laws.

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

According to the Draft Law and other information available publicly, the approach of GDPR implementation in Lithuania is not to introduce many derogations from the GDPR, instead seeking to rely on the provisions set out therein.

The Draft Law, for the most part, sets out provisions on procedural matters such as those related to filing complaints and status and functions of the State Data Protection Inspectorate (hereinafter – the **Inspectorate**). A few provisions regarding processing of employees' or potential employees' data and processing of personal code are provided in the Draft Law, but they do not contain any drastic differences from the GDPR. The Draft Law also provides that the minimum age required to be able to provide consent with relation to information society services is 14.

The Draft Law provides no provisions on processing of special categories of personal data, health data or processing for research purposes, whatsoever. No derogations under article 89 of the GDPR are proposed either. It must be noted that the Draft Law may still be changed and new provisions may be introduced. They can also be introduced after the GDPR comes into effect.

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

The main concern is that the lack of clarifying local legislation will lead to ambiguity in certain matters where the provisions of GDPR are not specific enough, however, our view on the Draft Law is generally positive. By not introducing many local derogations from the GDPR, Lithuanian data protection law will stay more in line with the EU legislative framework.

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c. The national data processing authority

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

With some exceptions, the Inspectorate[8] is responsible for supervision of all personal data protection matters in Lithuania, mainly for the supervision and control of enforcement of the Data Protection Law and for section IX "Personal data processing and privacy security" of the Law on Electronic Communications of the Republic of Lithuania.

The Inspectorate is responsible for: examining requests of persons; examining complaints and reports by persons, checking the lawfulness of personal data processing based thereon and taking decisions concerning violations in personal data processing; checking the lawfulness of personal data processing and taking decisions concerning violations in personal data processing; granting authorisations to data controllers for the transfer of personal data to data recipients in third countries; consulting data subjects, data controllers and data processors, other persons regarding the protection of personal data and privacy; also drawing up methodological recommendations on the protection of personal data and publishing them on the Internet; and other functions.

The Data Protection Law contains provisions on processing of personal data for scientific research purposes as well as provisions on processing of special categories of personal data, including health data. The main function of the Inspectorate in relation to medical or scientific research and/or processing of health data is the requirement of prior check procedure performed by the Inspectorate. Data processing form medical or scientific research or processing of health data may only start after such prior check is performed and after the Inspectorate issues a permit for such processing.

The requirement to notify the Inspectorate about data processing and function of prior check by the Inspectorate will no longer be applicable after the GDPR comes into effect, therefore this is not mentioned in the questionnaire any further. However, please note that in certain cases GDPR will require prior consultations with the Inspectorate, which likely may apply to use of health data for medical research.

Other relevant authority is the Lithuanian Bioethics Committee[9]. The Lithuanian Bioethics Committee is a governmental institution, which aims to promote and protect human rights and dignity in the field of healthcare. They take responsibility for the two broad areas of activities: informing biomedical community and general public on ethical issues and moral dilemmas arising in the context of modern health care; and facilitating the protection of patients' rights in the field of biomedical research and coordinating the ethical review of biomedical research projects in Lithuania. The institution is extremely important in the context of this study considering that, according to the Biomedical Research Law, the Lithuanian Bioethics Committee issues approvals to conduct biomedical research. Lithuanian Bioethics Committee consists of nine members, of whom five experts shall be professionals of biomedical sciences and four – professionals holding a degree in the area of social sciences or humanities.

[8] https://www.ada.lt/

[9] http://bioetika.sam.lt/

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Regional biomedical research ethics committees shall be established under universities offering three-cycle medical studies and shall consist of: two representatives of biomedical sciences holding a scientific degree and two representatives of social sciences or humanities holding a scientific degree, appointed by the university under which a regional biomedical research ethics committee has been formed; three health care professionals from the health care institutions operating in the area; and a professional of social sciences or humanities, appointed by the Minister of Health; and one member appointed by patients' organisations. Under Article 20 of the Biomedical Research Law, regional bioethics research committees are also authorised to issue approvals to conduct biomedical research.

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

According to the Draft Law, the general role and functions of the Inspectorate shall remain similar to those set out in the current Data Protection Law. As for the Inspectorate's role related to supervision of processing of health data or processing for scientific research purposes, the Draft Law provides no specific provisions. However, as already mentioned, it will no longer be required to notify the Inspectorate in the case of processing of personal data by automatic means and the Inspectorate will no longer conduct prior checking and will no longer manage the State Personal Data Controller's Register.

Under GDPR, it is likely that processing of health data for research purposes would require privacy impact assessment and prior consultation with the Inspectorate under articles 35, 36 of the GDPR.

2. Transposition of Article 8.4 of Directive 95/46

Article 8 of Directive 95/46 prohibits, in principle, the processing of special categories of personal data concerning health. Article 8.2 lists a series of exceptions to this general prohibition. Article 8.4 states "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".

When transposing Directive 95/46 did your national legislator or supervisory authority make use of the power granted to Member States in Article 8.4 of the Directive? Did the legislator use this provision to insert any additional (i.e. additional to the exceptions listed in the Directive) exemption (to the prohibition to process health data) for the processing of health data for research purposes?

If yes, how is such an exemption formulated? Please explain.

a. Transposition of Article 8.4 of the Directive 95/46

What are the exceptions to the prohibition of processing sensitive data? Do any of these exceptions address scientific research in the field of health?

The Data Protection Law which implements the Directive 95/46 allows the processing of special categories of personal data in cases set out in the Directive 95/46 and if: 1) the data are necessary, in the cases laid down in laws, to prevent and investigate criminal or other unlawful acts; 2) the data are necessary for a court hearing; 3) it is a legal obligation of the data controller under laws to process such data.

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Furthermore, the Data Protection Law permits processing of personal data on a person's health by an authorised health care professional and for scientific research purposes, including scientific medical research purposes.

How is such an exception formulated, and does it set out specific conditions?

Processing of personal data for scientific research purposes is allowed under Article 12 of the Data Protection Law on the condition that data subject has given his consent. However, it is also foreseen that personal data may be processed without consent upon giving a notice to the Inspectorate, in which case the Inspectorate must carry out a prior checking.

Other conditions of processing personal data for scientific research include the obligation to alter personal data immediately in a manner which makes it impossible to identify the data subject after the personal data has been used and the prohibition to process personal data collected and stored for the purposes of scientific research for any other purposes.

Article 10 sets out additional rules on processing of health data, allowing to process health data by authorised health care professionals, subject to professional secrecy, the Data Protection Law, the laws regulating patients' rights and other legal acts. The processing of personal data for scientific medical research purposes also requires to provide a notice to the Inspectorate and for the Inspectorate to perform a prior checking.

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?

Currently applicable Data Protection Law provides no additional provisions with respect to data processing for research in the field of health, other than those described above, but additional requirements are set out in the Patients' Rights Law and the Biomedical Research Law.

The Patients' Rights Law sets out the requirement to receive patient's consent in order to perform biomedical research and establishes the principle of the patient's interests having priority over the scientific interests. The Patients' Rights Law does not go into much detail regarding biomedical research but rather refers to the Biomedical Research Law.

The Biomedical Research Law sets out requirements for and principles of the ethics of biomedical research, a procedure for issuing approvals to conduct biomedical research, a procedure for controlling the conducting of biomedical research and liability for violation of these requirements etc. It is notable that the Biomedical Research Law also establishes the principle that the interests of the human being prevail over the interests of society and science.

According to the Biomedical Research Law, biomedical research may only be conducted if:

1) biomedical research has scientific and practical merit;

2) biomedical research cannot be substituted by other types of research which do not involve human research;

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3) protection of interests of the subject and confidentiality of information about the subject has been ensured;

4) free consent of the subject has been obtained;

5) refusal to give consent shall not strip the subject of the right to receive medical care;

6) in case of clinical trials, sufficient data related to pre-clinical trial research have been submitted;

7) the risk and inconvenience to the research subject is not higher than the benefits of the research;

8) the third-party insurance against possible damage to the subject is provided in the cases where in the cases of conducting of a clinical trial on a medicinal product, a clinical trial of a medical device or any other biomedical research in which the participant is, for research purposes, made subject to interventional research methods posing a risk to the subject's health and/or other harm;

9) the documents granting the right to conduct a biomedical research have been obtained;

10) there are no prohibitions against it in other laws.

Biomedical research is defined by the Biomedical Research Law as verification of hypotheses of biomedical sciences by means of methods of scientific research pursuing the aim of developing scientific knowledge about human health, diseases, diagnosis, medical treatment or prevention thereof. In our understanding, AEGLE project is likely to be considered a biomedical research project. Biomedical research may be undertaken on living or deceased human subjects or their groups, a human embryo, a human foetus, a human biological sample and health information.

Another important element related to biomedical research is the activity of biobanks. Under the Biomedical Research Law, biobank means a public legal person acting in the capacity of a budgetary or public establishment and holding a licence for personal health care services, including the right to process human biological samples and health information for the purposes specified in the Biomedical Research Law and conducting of biomedical research. Biobanks are bound by the requirements of the Biomedical Research Law, the Data Protection Law and the Law on Health Care Institutions of the Republic of Lithuania[10] and must respect the rights and freedoms of individuals as well as observe the principles of transparency, reliability, data security and openness. Biobanks are considered health care institutions and therefore must also receive a licence in order to conduct their activities.

Biobanks are entitled:

1) to be sponsors of biomedical research and to conduct biomedical research;

2) to cooperate, in accordance with the procedure laid down by legal acts, with biobanks of the European Union Member States, other states of the European Economic Area and third countries and international organisations and to participate in activities thereof;

3) to obtain health information in accordance with the procedure laid down in Article 15 of the Biomedical Research Law.

Article 15 of the Biomedical Research Law allows, upon the receipt of a person's consent, for a biobank to obtain the health information of a person whose human biological sample and health information are processed in the biobank from health care institutions, registers and/or state information systems. A biobank shall have the right to obtain

[10] https://e-seimas.lrs.lt/portal/legalAct/lt/TAD/TAIS.29546/iJMoCbrjiQ; https://e-seimas.lrs.lt/portal/legalAct/lt/TAD/TAIS.34572?jfwid=dg8d2q6l9

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health information also from other legal persons indicated in a person's consent to biobanking, where such health information is not available in registers and/or state information systems and to health care institutions, or if its provision from health care institutions would require unreasonably high material costs and/or time.

Biobanks are important because they are entitled to obtain and process health information and provide this information to the sponsor of biomedical research for the purposes of conducting biomedical research. In this case, if the objectives of the provision of the human biological samples and health information correspond to the scope of a person's consent to biobanking given by the person concerned, the researcher is not required to collect data subjects' consents.

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

According to the current Data Protection Law, researchers are exempt from the obligation to inform data subjects about processing of their personal data for research purposes where the disclosure of such information proves impossible or involves a disproportionate effort (owing to a large number of data recipients, the outdated character of the data and excessively large expenses) or where the procedure for collecting and disclosing of data is laid down by law. However, in such cases, the data controller must notify the Inspectorate thereof and the Inspectorate must carry out a prior checking.

Also, despite the requirement to process personal data for research purposes and health data only with data subjects' consent, the Data Protection Law provides a possibility to do so without the data subject's consent, however only upon giving a notice to the Inspectorate. In this case, the Inspectorate must carry out a prior checking.

As regards specifically the biomedical research, the Biomedical Research Law also provides that authorities may take a decision on whether a person's consent to participate in research is necessary for conducting biomedical research on a person's biological sample and/or health information which has been obtained for the purpose of provision of personal health care, statistical or other purposes, enabling in certain situations to conduct biomedical research without subjects' consents.

With regard to biobank data, if the objectives of the provision of the human biological samples and health information correspond to the scope of a person's consent to biobanking given by the person concerned, the researcher is not required to collect data subjects' consents.

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

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

No safeguards other than those mentioned in section II of this questionnaire are set out in the Data Protection Law with respect to general scientific research, but, as provided above, other laws may provide additional safeguards, such as those provided by the Biomedical Research Law, as stated in section II of this questionnaire.

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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?

General prohibition to share health data and its confidentiality is set out in a number of legal acts, including in the Civil Code of the Republic of Lithuania, the Data Protection Law and the Patients' Rights Law. Health data can only be transferred and/or used for research purposes under exemptions from the general prohibition provided by laws, as described in answers to this questionnaire above.

Although in some cases health data can be processed without the data subject's consent, it generally does require an explicit and informed consent. In fact, the Biomedical Research Law provides specific requirements for the consent to participate in biomedical research and the consent to participate in biobanking. The person's consent to participate in research/biobanking must meet all of the following conditions:

1) the person's consent to participate in research/biobanking has been given by a person capable of expressing his will;

2) the person's consent to participate in research/biobanking has been given after having been duly informed;

3) the person's consent to participate in research/biobanking has been given freely by the person;

4) the person's consent to participate in research/biobanking meets detailed requirements for the content of a person's consent as set forth by the Minister of Health. Detailed requirements for informed consent forms are set out in separate legal acts.[11][12]

As regards deceased data subjects, the Biomedical Research Law does allow processing of data of deceased data subjects, subject to general requirements set out in the Biomedical Research Law and specific consent requirements described further. Where prior to their death the subject did not give consent to participate in research or did not withdraw it, the subject's consent to undertake biomedical research on the deceased person's human biological samples and health information shall be given by the surviving spouse or, where the person was not married, marriage has ceased, the spouse has been declared missing or the spouses lived separately – by one of his close relatives in the following order of priority: parents/adoptive parents, children/adopted children of legal age, brothers/sisters, grandparents, grandchildren. If the consent is given by one of the above-mentioned persons in the order of priority, the consent of other close relatives of the deceased shall not be asked for. If one of the above-mentioned persons expresses his objection in the order of priority, it shall be prohibited to undertake biomedical research on a human biological sample/samples and health information of the deceased. Similar principles are applicable with respect participation in biobanking.

Finally, with respect to minors and persons subject to guardianship, the Biomedical Research Law also sets out special conditions. As regards minors, having regard to a minor's age and capacity to understand, the minor must be duly provided with the information on the research as set out in the Biomedical Research Law. The subject's consent to participate in research in respect of a minor's participation in biomedical research shall be given by the minor's legal representatives, however if the minor who is capable of understanding the information provided to him

[11] https://e-seimas.lrs.lt/portal/legalAct/lt/TAD/b9895bf0ba3811e5be9bf78e07ed6470?positionInSearchResults=0&searchModelUUID=a4086949-b1f3-429e-8197-870c6122d393

[12] https://www.e-tar.lt/portal/lt/legalAct/aa41cb30c5b111e583a295d9366c7ab3

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expresses his wish not to participate in the biomedical research or, if the minor is already involved in such a biomedical research, to discontinue his participation therein, the minor's participation in the research shall not commence or shall be terminated, unless this is contrary to the interests of the minor. Similar principles are applicable with respect to a minor's participation in biobanking.

As for persons subject to guardianship or persons who for health reasons cannot be considered as being capable of rationally assessing their interests, their consent shall be given by the person's spouse or, if the person is not married, marriage has ceased, the spouse has been declared missing or the spouses lived separately – by one of the person's parents/adoptive parents or by one of children/adopted children who are of legal age or, when a person is adjudged as incapacitated – by his guardian or, when the person's capacity is limited – by his caretaker. The subject must, having regard to his capacity to understand, be provided with the information on the research. The subject conducting the research shall take into account the wish of the subject capable of understanding the information provided to him not to participate in biomedical research or, if the subject is already involved in such biomedical research, the wish to withdraw from it. Upon receiving objection of one of the mentioned persons in the order of priority, it shall be prohibited to undertake biomedical research on the person who for health reasons cannot be considered as capable of rationally assessing his interests.

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

Although the Data Protection Law in some cases exempts researchers from the obligation to inform data subjects, the Biomedical Research Law essentially disregards this exemption and imposes a duty to inform subjects of biomedical research and to provide them with (also note the informed consent form requirements described in the section above):

1) the purpose of biomedical research;

2) the design of biomedical research;

3) the methods applicable in the course of biomedical research;

4) an approval to conduct biomedical research issued by the Lithuanian Bioethics Committee or a regional biomedical research ethics committee;

5) foreseeable benefits of biomedical research to the subject;

6) rights of the subject;

7) risks posed and burden imposed by biomedical research to the subject;

8) the procedure for compensating for the damage which could be caused in the course of biomedical research;

9) the right to withdraw his consent to participate in research at any time, providing to him information about the consequences of such withdrawal;

10) guarantees of confidentiality of health information.

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

Taking into consideration that processing of health data for scientific research purposes primarily concerns data protection regime, penalties set out in data protection may be applicable. According to Article 82 of the Code of Administrative Offenses of the Republic of Lithuania, infringement of the requirements set out in the Law on Legal Protection of Personal Data of the Republic of Lithuania may lead to a fine of EUR 150 to EUR 580; and EUR 300 to EUR 1150 for heads of legal entities or other responsible persons. Repeated offenses may lead to fines of EUR 550 to EUR 1200; and EUR 1100 to EUR 3000 for heads of legal entities or other responsible persons.

It is also to be noted that the Data Protection Inspectorate of the Republic of Lithuania are authorised to obtain access, subject to a prior notice in writing, or without a prior notice where the lawfulness of personal data processing is to be checked in response to a complaint, to premises of the person being checked and to make recommendations and give instructions to data controllers on personal data processing and protection issues.

Data subjects whose rights have been violated are also entitled to claim compensation for pecuniary and non-pecuniary damage caused by unlawful data processing.

After the GDPR comes into effect, administrative fines and penalties set out in the GDPR will be applicable.

Furthermore, depending on the type of a specific infringement, laws related to patients' rights may be applicable, in which case the patients may request reimbursement for the damage caused. If the research has not incurred either pecuniary or non-pecuniary damage to the subject's health, the conducting of a biomedical research without an authorisation or not in compliance with the requirements set forth by legal acts shall be held equivalent to an act of malpractice.

In extreme cases, Article 308[1] of the Criminal Code of the Republic of Lithuania may be applicable, which sets out liability for prohibited biomedical research performed on humans or human embryos. Penalties include a fine, restriction of liberty, arrest or a custodial sentence for a term of up to two years.

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

This section 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?

Additionally to the requirements set out in section II.B. of this questionnaire, the Biomedical Research Law requires to obtain an authorisation of the Lithuanian Bioethics Committee or a regional biomedical research ethics committee in order to perform biomedical research (where the biomedical research is planned to be conducted at the research sites located solely within the territory attributed to activities of the respective regional biomedical research ethics committee).

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In order to obtain an approval to conduct biomedical research, the sponsor of the research, an authorised representative thereof and/or the principal investigator (natural person conducting biomedical research, who meets the requirements set forth by the Biomedical Research Law) shall submit to the Lithuanian Bioethics Committee or to a regional biomedical research ethics committee the list of documents approved by the Minister of Health[13]. The documents are considered and the approval to conduct biomedical research is issued or a reasoned refusal to issue it is given not later than within 45 calendar days from the receipt of all duly executed documents.

A state fee of the established amount shall be paid for expert examination of the documents submitted for the issuance of an approval to conduct biomedical research and for the issuance of approvals itself. Current amount of the state fee ranges from EUR 525 to EUR 980, depending on the type of examination and approval required[14].

Furthermore, the sponsor of medical research and the principal investigator must insure their civil liability against any pecuniary and non-pecuniary damage incurred as a result of impairment to the subject's health or the subject's death by entering with insurers into contracts of compulsory insurance against civil liability of the sponsor of biomedical research and the principal investigator. This requirement shall apply only in the cases of conducting of a clinical trial on a medicinal product or any other biomedical research in which the participant is, for the purposes of biomedical research, made subject to interventional research methods posing a risk to the subject's health. The conduct of a clinical trial on a medicinal product or any other biomedical research in which the participant is, for the purposes of biomedical research, made subject to interventional research methods having only a slightly detrimental and temporary impact on his health shall also be permitted if a contract of insurance of civil liability for damage caused to patients of a health care institution which itself or whose employee is the sponsor of such research or whose employee is an investigator in such research provides for compensation for the damage that may result from such research.

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 general rule set out in the Data Protection Law is that personal data must be collected for specified and legitimate purposes and later cannot be processed for purposes incompatible with the purposes determined before the personal data is collected.

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

The Data Protection Law provides that personal data collected for other purposes may be processed for scientific research purposes in cases laid down in laws, provided that adequate data protection measures are established. Some of these data protection measures are established in the Data Protection Law itself (i.e., the requirement to alter personal data immediately in a manner which makes it impossible to identify the data subject after the personal

[13] https://e-seimas.lrs.lt/portal/legalAct/lt/TAD/TAIS.312804/jeZNhoYcVM

[14] https://e-seimas.lrs.lt/portal/legalAct/lt/TAD/TAIS.116101/lFNMMMlKah

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data has been used), others are established in laws relevant to a specific field, such as the safeguards established in the Biomedical Research Law, applicable to biomedical research.

What are the rights of the data subject when it comes to such further processing? What about the data subject's rights and further processing for scientific research purposes?

The only exceptions to the rights of the data subject provided for in the Data Protection Law are the exemptions to the obligation to inform data subjects regarding processing of their data for research purposes (where the disclosure of such information proves impossible or involves a disproportionate effort) and the obligation to receive consent of data subjects (where authorities permit processing without consent). Otherwise the common rights of the data subject are applicable.

With regard to biobank data, if the objectives of the provision of the human biological samples and health information correspond to the scope of a person's consent to biobanking given by the person concerned, the researcher is not required to collect data subjects' consents.

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

Under the GDPR the processing of health data for research purposes is regulated by Article 9(2)(j), which authorises the processing of health data if this "processing is necessary for archiving purposes in the public interest, scientific or historical research purposes or statistical purposes in accordance with Article 89(1) based on Union or Member State law which shall be proportionate to the aim pursued, respect the essence of the right to data protection and provide for suitable and specific measures to safeguard the fundamental rights and the interests of the data subject" (emphasis added), and is combined with Article 89(1) ("Processing for archiving purposes in the public interest, scientific or historical research purposes or statistical purposes, shall be subject to appropriate safeguards, in accordance with this Regulation, for the rights and freedoms of the data subject. Those safeguards shall ensure that technical and organisational measures are in place in particular in order to ensure respect for the principle of data minimisation. Those measures may include pseudonymisation provided that those purposes can be fulfilled in that manner. Where those purposes can be fulfilled by further processing which does not permit or no longer permits the identification of data subjects, those purposes shall be fulfilled in that manner").

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?

There are currently no amendments proposed in the Draft Law or other draft acts as regards implementation of Article 9(2)(j) of the GDPR.

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

The current Data Protection Law will be, for the most part, abolished and the data protection regime in Lithuania will be based on GDPR. Based on the current Draft Law, there will be very little local deviations from the GDPR. With regard to scientific research, the Draft Law provides no local provisions whatsoever. This means that the currently applicable provisions on notification of the Inspectorate and the requirement of prior checking by the Inspectorate will no longer apply.

While the general data protection regime will be based on GDPR, meaning that specific local provisions on notifications, prior-checking, safeguards related to scientific research, etc., will no longer apply, the specific regime applicable to biomedical research will not be substantially affected by the GDPR. Therefore conditions set out in the Patients' Rights Law and especially conditions set out in the Biomedical Research Law will be applicable despite GDPR, requiring researchers to complete the required steps and comply with obligations such as the aforementioned requirement to receive an authorisation of the Lithuanian Bioethics Committee or a regional biomedical research ethics committee.

Currently the Draft Law provides no local provisions on the rights of the data subject and the obligations of the controller that would deviate materially from the GDPR.

5. Further processing for research purposes under the GDPR

Further processing of personal data for scientific research purposes is regulated in the GDPR by Article 5(1)(b) ("further processing for archiving purposes in the public interest, scientific or historical research purposes or statistical purposes shall, in accordance with Article 89(1), not be considered to be incompatible with the initial purposes") and Article 89(1) ("Processing for archiving purposes in the public interest, scientific or historical research purposes or statistical purposes, shall be subject to appropriate safeguards, in accordance with this Regulation, for the rights and freedoms of the data subject. Those safeguards shall ensure that technical and organisational measures are in place in particular in order to ensure respect for the principle of data minimisation. Those measures may include pseudonymisation provided that those purposes can be fulfilled in that manner. Where those purposes can be fulfilled by further processing which does not permit or no longer permits the identification of data subjects, those purposes shall be fulfilled in that manner").

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

Currently the Draft Law provides no local provisions on further processing of personal data, thus the GDPR will be directly applicable. However, as mentioned in the section above, specific health related regime will still be applicable

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and further processing of health data for research purposes will be subject to conditions set out in the Biomedical Research Law.

6. Health data sources for research purposes

This section seeks to identify information on the availability of health data for research purposes. Do public authorities or other entities facilitate the availability of health data for research purposes? In what way? Under what conditions?

a. Sources of data and their regulation

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

Health data can potentially be gathered from any number of different sources, including directly from data subjects, health professionals or institutions and databases, as described in more detail below.

- **DIRECT COLLECTION FROM THE PATIENTS:**

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

Under the current legal framework, collecting and processing health data for research purposes directly from data subjects is subject first and foremost to having a lawful basis under Article 5 of the Data Protection Law. In this particular case, the consent of the data subject could be considered the most feasible lawful basis for processing of health data. Indeed, Article 12 of the Data Protection Law allows processing of personal data for research purposes on the condition that data subject's consent is received, unless the Inspectorate is notified and prior checking is performed.

Furthermore, the Data Protection Law requires, in cases where personal data on a person's health is processed by automatic means and for scientific medical research purposes, to give a prior notice to the Inspectorate, which must then perform a prior checking (regardless of consent).

If it is intended to perform biomedical research, the researcher is additionally required to obtain an authorisation of the Lithuanian Bioethics Committee or a regional biomedical research ethics committee, insure its liability (where applicable), provide the data subject with sufficient information about the research and receive the subject's consent in accordance with the requirements of the Biomedical Research Law and related acts.

However, in cases where a person's biological sample or other health information has been obtained for purposes other than scientific research and where it has been obtained prior to applying for undertaking of research, the Lithuanian Bioethics Committee or a regional biomedical research ethics committee when issuing an approval to conduct biomedical research can decide to exempt the researcher from the obligation to receive the consent of the data subject. Although this is more relevant in situations where the data is not collected directly from the data subject and it is intended to rely on the exemption of further processing for scientific purposes.

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

Based on the current Draft Law, the obligation to give a prior notice to the Inspectorate and the prior checking provisions will no longer be applicable. However, it will still be required to have a lawful basis for processing of health data under Article 9 of the GDPR. In this particular case, the consent of the data subject could be considered the most feasible lawful basis for processing of health data, or legal ground established in article 9.2.f could also be relied upon.

If it is intended to perform biomedical research, the requirements related to receiving an authorisation to perform biomedical research and other specific requirements such as specific provisions of data subject's informed consent will still be applicable in accordance with the Biomedical Research Law. Only the current Data Protection Law provisions will cease being in effect.

- **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.

Essentially, similar rules are applicable to those concerning data collection directly from data subjects. Similarly to collecting data and processing data directly from data subjects, collecting and processing of personal data from health professionals and health institutions is also subject to having a lawful basis for the processing. As an additional requirement, due to not receiving personal data directly from the subject, data transfer agreement between the health institution and the researcher must be concluded in accordance with Article 6 of the Data Protection Law.

Furthermore, the Data Protection Law requires, in cases where personal data on a person's health is processed by automatic means and for scientific medical research purposes, to give a prior notice to the Inspectorate, which must then perform a prior checking (regardless of consent).

If it is intended to perform biomedical research, the researcher is additionally required to obtain an authorisation of the Lithuanian Bioethics Committee or a regional biomedical research ethics committee, insure its liability (where applicable), provide the data subject with sufficient information about the research and receive the subject's consent in accordance with the requirements of the Biomedical Research Law and related acts.

However, in cases where a person's biological sample or other health information has been obtained for purposes other than scientific research and where it has been obtained prior to applying for undertaking of research, the Lithuanian Bioethics Committee or a regional biomedical research ethics committee when issuing an approval to conduct biomedical research can decide to exempt the researcher from the obligation to receive the consent of the data subject. The possibility to receive this exemption is especially important with respect to receiving data form sources other than the data subject, it is intended to rely on the exemption of further processing for scientific purposes.

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

Based on the current Draft Law, the obligation to give a prior notice to the Inspectorate and the prior checking provisions will no longer be applicable. However, it will still be required to have a lawful basis for processing of health data under Article 9 of the GDPR.

If it is intended to perform biomedical research, the requirements related to receiving an authorisation to perform biomedical research and other specific requirements such as specific provisions of data subject's informed consent will still be applicable in accordance with the Biomedical Research Law. The possibility to receive an exemption from the obligation to receive the consent of the data subject in case of biomedical research, as described above, will also stay in force. Only the current Data Protection Law provisions will cease being in effect.

- **PRIVATE AND PUBLIC DATABASES; BIOBANKS**

Conditions similar to those described for collection from health professionals and health institutions are applicable. Local law provides no additional specific regulation with respect to databases, except where it relates to biobanks, as described further.

As already mentioned in this questionnaire, biobank is a public legal person acting in the capacity of a budgetary or public establishment and holding a licence for personal health care services, including the right to process human biological samples and health information for the purposes specified in the Biomedical Research Law and conducting of biomedical research.

They are entitled to obtain health information from health care institutions, registers and/or state information systems as well as from other legal persons indicated in a person's consent to biobanking, where such health information is not available in registers and/or state information systems and to health care institutions or its provision would require from health care institutions unreasonably high material costs and/or time.

Although biobanks are allowed to collect health data and provide it to researchers, this activity is subject authorisation requirements regardless. Data subjects must consent to activities of biobanking and the biobanking consent must meet conditions which are similar to conditions applicable to biomedical research consent. Detailed requirements for the content of a person's consent to biobanking are set forth by the Minister of Health.[15]

The human biological samples and health information processed in a biobank may be provided for the sponsor of biomedical research, his authorised representative or the principal investigator upon receipt of an approval to conduct biomedical research by the Lithuanian Bioethics Committee or a regional biomedical research ethics committee. An approval for the provision of the human biological samples and/or health information processed in a biobank shall be issued where the Lithuanian Bioethics Committee decides that objectives of the provision of the human biological samples and health information correspond to the scope of a person's consent to biobanking given by the person concerned and the required authorisations are held by the recipient of health information. If the objectives of the provision of the human biological samples and health information correspond to the scope of a person's consent to biobanking given by the person concerned, the researcher is not required to separately collect data subjects' consents.

[15] https://www.e-tar.lt/portal/lt/legalAct/aa41cb30c5b111e583a295d9366c7ab3

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Under GDPR, the provisions related to biobanks as set out in the Biomedical Research Law shall remain in effect according to currently available information.

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

This section seeks a short summary of the rules to be observed in your country by a hypothetical researcher involved in the AEGLE project. The objective is to obtain a practical response for informing such a researcher as clearly as possible.

1. Type 2 diabetes

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

Current legal framework: which procedural or other steps would the researcher have to follow to use this data for 'big data' analytics on the AEGLE platform? Is a new ethical or other approval required? From which body? Should the patient be informed about the new research project? Is a new patient consent, specifically focusing on the precise research project, required?

According to currently applicable Data Protection Law, the Inspectorate must be notified about processing of personal data on a person's health by automatic means for scientific medical research purposes, which must then perform a prior checking.

Processing of personal health data for scientific research purposes requires data subject's consent. A generic consent to scientific research cannot cover future research, because the data subject must be duly informed about the purposes of the collection of data and its use. A generic consent cannot be considered legitimate, as the data subject cannot consent to processing which they have no information about. In light of this, a new patient consent focusing specifically on the precise research project is required, including provision of the required information to the patient regarding the research. The informed consent must follow the requirements set out in the Biomedical Research Law and related sub-statutory acts, as described in more detail in other sections of this questionnaire.

Having in mind that it is intended to process personal health information for biomedical research purposes, additionally an approval is required from the Lithuanian Bioethics Committee (or, if applicable, regional biomedical research ethics committee).

Considering that in this scenario it is intended to process health information which has been obtained for the purpose of provision of personal health care, it is possible to request in the application for approval submitted to the Lithuanian Bioethics Committee to exempt the researcher from the duty to receive data subjects' consents.

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

There will no longer be a requirement to notify the Inspectorate and have them perform a prior checking. Otherwise the requirements set out in the Biomedical Research Law shall continue to be applicable.

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2. Intensive Care Unit (ICU)

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

Current legal framework: which procedural or other steps would the researcher have to follow to use this data for 'big data' analytics on the AEGLE platform? Is a new ethical or other type of approval required? From which body? Should the patient be informed about the new research project?

According to currently applicable Data Protection Law, the Inspectorate must be notified about processing of personal data on a person's health by automatic means for scientific medical research purposes, which must then perform a prior checking.

Processing of personal health data for scientific research purposes requires data subject's consent. In light of this, patient's consent on the research project is required, including provision of the required information to the patient regarding the research. The informed consent must follow the requirements set out in the Biomedical Research Law and related sub-statutory acts, as described in more detail in other sections of this questionnaire.

Having in mind that it is intended to process personal health information for biomedical research purposes, additionally an approval is required from the Lithuanian Bioethics Committee (or, if applicable, regional biomedical research ethics committee).

Considering that in this scenario it is intended to process health information which has been obtained for the purpose of provision of personal health care, it is possible to request in the application for approval submitted to the Lithuanian Bioethics Committee to exempt the researcher from the duty to receive data subjects' consents.

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

There will no longer be a requirement to notify the Inspectorate and have them perform a prior checking. Otherwise the requirements set out in the Biomedical Research Law shall continue to be applicable.

3. Chronic Lymphocytic Leukaemia (CLL)

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

Current legal framework: which procedural or other steps would the researcher have to follow to use this data for 'big data' analytics on the AEGLE platform? Is a new ethical or other approval required? From which body? Should the patient be informed about the new research project?

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According to currently applicable Data Protection Law, the Inspectorate must be notified about processing of personal data on a person's health by automatic means for scientific medical research purposes, which must then perform a prior checking.

The researcher is not required to receive data subject's consent for processing of personal health data for scientific research purposes if the health data is received from biobanks, however the provision of the human biological samples and/or health information processed in a biobank is nevertheless subject to approval of the Lithuanian Bioethics Committee. Processing of health data for a specific research project is possible and the approval is issued only on the condition that objectives of the provision of the human biological samples and health information correspond to the scope of a person's consent to biobanking given by the person concerned.

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

There will no longer be a requirement to notify the Inspectorate and have them perform a prior checking. Otherwise the requirements set out in the Biomedical Research Law shall continue to be applicable.

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