AEGLE

An Analytics Framework for Integrated and Personalized Healthcare Services in Europe

www.aegle-uhealth.eu

AEGLE in your country

How does your country process health data after GDPR?

Estonia

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

The Estonian 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 Cathriin Torop for SORAINEN
in Tallinn, Estonia, 5 April 2018

This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 644906

Contents

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

Partners
EXUS AE (Coordinator), ICCS, KINGSTON, CERTH, Maxeler Tecnologies Limited, UPPSALA UNIVERSITET, UNISR, Time.Lex, EUR, CHS, LOBA, PAGNI, GNUBILA FRANCE, NTU

1. Overview of the legal framework (ESTONIA)

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

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

1. Personal Data Protection Act[1] (hereinafter the **PDPA**): the general personal data protection act in Estonia. It prescribes the conditions and procedure for processing of personal data (including sensitive personal data), the procedure for the exercise of state supervision and administrative supervision upon processing of personal data and liability for the violation of the requirements for processing of personal data. PDPA was first adopted in 1996, with a new redaction entering into force in 2004 for the transposition of Directive 95/46/EC. Currently valid PDPA implements and reflects Directive 95/46/EC.

With the entry into force of the GDPR, new redaction of the PDPA will be introduced (hereinafter the **NDPA**). For the purposes of the following analysis, NDPA refers to the latest draft act of the PDPA published on 23 March 2018. The planned entry into force of the NDPA is on 25 May 2018. It is possible that in the course of legislative procedure, the draft will be amended and changed, and therefore we recommend revising the following advice when the NDPA has been finally adopted.

2. Public Information Act[2] (hereinafter the **PIA**): general act which governs, inter alia, the process and criteria for establishing public databases and disclosure of personal data to and from these databases. The Health Information System is also one of such databases (see below).

3. Health Services Organisation Act[3] (hereinafter the **HSOA**): regulates organisation of and the requirements for the provision of health services, and the procedure for the management, financing and supervision of health care. The HSOA also specifically regulates access to the Health Information System.

4. Public Health Act[4]: describes the performance of duties by the state, local governments, legal persons in public law, legal persons in private law and natural persons, and through the system of national and local measures for the protection of human health, prevention of diseases and promoting health,.

5. Human Genes Research Act[5]: regulates the establishment and maintenance of a Gene Bank and its operation, including of certain data.

[1] Authentic text (available in English): Isikuandmete kaitse seadus[1] (https://www.riigiteataja.ee/en/eli/507032016001/consolide)

[2] Authentic text (available in English): Avaliku teabe seadus[1] (https://www.riigiteataja.ee/en/eli/516102017007/consolide)

[3] Authentic text (available in English): Tervishoiuteenuste korraldamise seadus (https://www.riigiteataja.ee/en/eli/508012018001/consolide)

[4] Authentic text (available in English): Rahvatervise seadus (https://www.riigiteataja.ee/en/eli/520122017004/consolide)

[5] Authentic text (available in English): Inimgeeniuuringute seadus (https://www.riigiteataja.ee/en/eli/518062014005/consolide)

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

Partners
EXUS AE (Coordinator), ICCS, KINGSTON, CERTH, Maxeler Tecnologies Limited, UPPSALA UNIVERSITET, UNISR, Time.Lex, EUR, CHS, LOBA, PAGNI, GNUBILA FRANCE, NTU

Other acts which are directly related to health care refer to the above-named regulations (especially PDPA and PIA) in terms of processing of health data.

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

Yes, shared health records exist in Estonia. Estonia has a Health Information System (hereinafter the **HIS**) – a database forming part of the State Information System. HIS includes data related to health care are processed for entry into and performance of contracts for the provision of health services, for guaranteeing the quality of health services and the rights of patients and for the protection of public health, including for maintaining registers concerning the state of health, for the organisation of health statistics and for the management of health care. Health Information System is regulated by the HSOA and Statute of Health Information System[6].

Both the health care provider and a participant (a student undergoing medical training or a resident physician) have access to personal data in the Health Information System for entry into and performance of a contract for the provision of health services. However, the patient can prohibit the access of a health care provider to the personal data of the patient in the HIS.

In addition to the previous, forensic expert of a state forensic institution has also access to the personal data in the HIS (for ascertaining the characteristics of injuries and for conducting forensic autopsy of a deceased person), and officials of the Ministry of Social Affairs are allowed to access the personal data from the HIS in order to make surveys, analyses and organise health statistics necessary for the management of health policy and performance of international obligations.

Under the currently valid PDPA, the officials of the Ministry of Social Affairs engaging in the analysis of data concerning health statistics and the employees of an institution administered by the Ministry of Social Affairs engaging in the health statistics have access to the certain personal data of a patient in the HIS in a way which does not enable the identification of a patient. Decoding of this data and processing of additional data for identification of a patient is prohibited. Under the implementing act of the NDPA, such specific right will be removed from HSOA as it will be covered by Article 89(1) of the GDPR.

Other persons have access to personal data in the HIS only if such right arises from law.

The ethics committee of HIS assesses whether the release of personal data from the HIS for the purposes of scientific research or statistics is necessary and justified. However, the assessment of the ethics committee is not legally binding. The ethics committee acts pursuant to generally recognised principles of medical ethics, personal data protection and international and national legislation. An application for release of personal data for the purposes of scientific research or statistic must be submitted to the chief processor of the HIS (i.e. Ministry of Social Affairs).

[6] Authentic text (in Estonian only): Tervise infosüsteemi põhimäärus: https://www.riigiteataja.ee/akt/106122016011

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

Partners
EXUS AE (Coordinator), ICCS, KINGSTON, CERTH, Maxeler Tecnologies Limited, UPPSALA UNIVERSITET, UNISR, Time.Lex, EUR, CHS, LOBA, PAGNI, GNUBILA FRANCE, NTU

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?

The PDPA currently in force will be declared invalid and NDPA is expected to enter into force on 25 May 2018. The NDPA will create a general framework and rules for processing of personal data to the extent Estonia has such legislative discretion under the GDPR.

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

Entirely new legislative text will be implemented, although the name of the legal act will remain the same and many principles will remain the same in essence (including the regulation on the use of personal data for scientific research and national statistics). The new act will mainly focus on the topics which are left into the discretion of national law under the GDPR.

In addition to the new revised NDPA, a separate implementing act is adopted, which implements amendments to all other legal acts which are affected by the implementation of the new legislative text and GDPR.

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

The NDPA regulates issues left in the discretion of member states, an also transposes Directive 2016/680 into national law. The act was preceded by the concept document “New legal framework of personal data protection” which was sent to stakeholders for expressing opinions in 2017. The draft act has currently been redrafted two times, with final draft published on 23 March 2018. It is likely that the current draft will see amendments in the legislative procedure. The NDPA still needs to be passed by the Government, followed by adoption procedure in the Parliament and proclamation by the President of the Republic.

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

The NDPA is rather simplistic and not well evaluated in details and the practical effects of the regulation. The process of the adoption has been badly managed with initially planned deadlines having elapsed during the process. Therefore, we consider it unlikely that the NDPA will enter into force by 25 May 2018.

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?

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

Partners
EXUS AE (Coordinator), ICCS, KINGSTON, CERTH, Maxeler Tecnologies Limited, UPPSALA UNIVERSITET, UNISR, Time.Lex, EUR, CHS, LOBA, PAGNI, GNUBILA FRANCE, NTU

Estonian personal data processing supervisory authority is the Estonian Data Protection Inspectorate (hereinafter the **EDPI**).[7] EDPI is an independent national supervising authority which conducts supervision over all types of personal data processing, and carries out activities of preventive nature to raise awareness of the public about the issues related to the personal data processing.

Under the currently valid PDPA, processing of personal data for scientific research or official statistics purposes without the consent of the data subject is permitted if the processor of the personal data has taken sufficient organisational, physical and information technology security measures for the protection of the personal data, has registered the processing of sensitive personal data and the EDPI has verified, before the commencement of the processing of the personal data, compliance with the requirements set out in law and has also heard the opinion of an ethics committee in the corresponding area (if such exists). Similar approval body role is attributed to the EDPI under the NDPA.

In addition to the previous, the EDPI is one of the supervisory authorities to conduct supervision over the operation of the HIS.

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

EDPI will be the national supervisory authority under the NDPA and GDPR. Compared to the current legislation, the role and tasks of the EDPI will be more explicit. In addition to the tasks under Article 57 of the GDPR, EDPI will register the contact details of the DPO-s, exercise state and administrative supervision over the compliance with the personal data processing requirements (with additional special state supervision measures available to the EDPI) and cooperate with European Data Protection Board.

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.

[7] http://www.aki.ee/en

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

Partners
EXUS AE (Coordinator), ICCS, KINGSTON, CERTH, Maxeler Tecnologies Limited, UPPSALA UNIVERSITET, UNISR, Time.Lex, EUR, CHS, LOBA, PAGNI, GNUBILA FRANCE, NTU

Under the currently valid PDPA, health data is defined as sensitive persona data. There is no general prohibition for the processing of sensitive personal data in the PDPA. Therefore, Estonian regulation diverges from Article 8 of Directive 95/46 by stipulating that processing of sensitive personal data is generally permitted if there is a valid legal basis for such processing. The law explicitly prescribes certain specific situations prescribed when processing of sensitive personal data is prohibited.

In addition, processing of sensitive personal is subject to some restrictions and requirements under the law. For example, the processor of sensitive personal data must appoint a person responsible for the protection of personal data or, as an alternative, register the processing of sensitive personal data with the EDPI. This requirement will be repealed with the.

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?

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

Processing of sensitive personal data is permitted if there is legal basis for such data processing. Such legal basis can be the consent of the data subject or derive from law.

In the context of processing sensitive personal for research purposes the data processing can be based on the consent of the data subject or, if there is no consent, permitted if the processor of the personal data has taken sufficient organisational, physical and information technology security measures for the protection of the personal data, has registered the processing of sensitive personal data and the EDPI has verified, before the commencement of the processing of the personal data, compliance with the requirements set out in the law and, if an ethics committee has been founded based on law in the corresponding area, has also heard the opinion of such committee.

Based on the NDPA, if the scientific research is based on special categories of data (i.e. health data), the ethics committee of specific field (or EDPI if there is no such ethics committee) must check the compliance of planned processing with the requirements under the law. This procedure is not applicable if the data has been pseudonymised or anonymised.

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?

No, such processing is governed by general principles of processing sensitive data for research purposes.

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

N/A

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

Partners
EXUS AE (Coordinator), ICCS, KINGSTON, CERTH, Maxeler Tecnologies Limited, UPPSALA UNIVERSITET, UNISR, Time.Lex, EUR, CHS, LOBA, PAGNI, GNUBILA FRANCE, NTU

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

As a general rule, data concerning a data subject may be processed without the consent of the data subject for the needs of scientific research only in coded form. Decoding and the possibility to decode is permitted only for the needs of further scientific research. The processor of the personal data must appoint a specific person who has access to the information allowing decoding.

Processing of data concerning a data subject without the person's consent for scientific research purposes in a format which enables identification of the data subject is permitted only if, after removal of the data enabling identification, the goals of data processing would not be achievable or achievement would be unreasonably difficult. In such case, the personal data of a data subject may be processed without the person's consent only if the person carrying out the scientific research finds that there is a predominant public interest for such processing and the volume of the obligations of the data subject is not changed on the basis of the processed personal data and the rights of the data subject are not excessively damaged in any other manner.

Processing of personal data for scientific research purposes without the consent of the data subject is permitted if the processor of the personal data has taken sufficient organisational, physical and information technology security measures for the protection of the personal data, has registered the processing of sensitive personal data and the EDPI has verified, before the commencement of the processing of the personal data, compliance with the requirements set out in law and, if an ethics committee has been founded based on law in the corresponding area, has also heard the opinion of such committee.

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?

Not in the context of scientific research. General requirements are applicable.

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

No specific requirements.

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?

General penalties apply. Under the currently valid PDPA, the penalties are up to EUR 32,000.

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

N/A. Regime applying to processing for research in the field of health is not a specific regime. Processing is ruled by the general regime (see section 0).

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

Partners
EXUS AE (Coordinator), ICCS, KINGSTON, CERTH, Maxeler Tecnologies Limited, UPPSALA UNIVERSITET, UNISR, Time.Lex, EUR, CHS, LOBA, PAGNI, GNUBILA FRANCE, NTU

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

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

The term has not been specifically defined. As a general rule, collected personal data may be only be processed for the purposes of scientific research regardless of the purpose for which the personal data were initially collected. Personal data collected for scientific research may be stored in coded form for the purposes of using it later for scientific research or official statistics.

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

There are no specifics for health data. The data must be coded and use of the data on later research must be compliant with the law (the same requirements are applicable as for any processing for scientific research purposes, see section 0).

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

General right as applicable to any type of processing.

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

No specific regulation from the currently valid PDPA or NDPA. General right as applicable to any type of processing.

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?

Processing health data for scientific purposes will remain under general regulation for processing special categories of data for scientific purposes. No specific regime will likely be implemented for health data.

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

Partners
EXUS AE (Coordinator), ICCS, KINGSTON, CERTH, Maxeler Tecnologies Limited, UPPSALA UNIVERSITET, UNISR, Time.Lex, EUR, CHS, LOBA, PAGNI, GNUBILA FRANCE, NTU

Under the NDPA, Article 9 and Article of 89 of the GDPR will be implemented in Chapter 2 of the act ("Processing of personal data on special grounds"). Processing of personal data for the purposes of scientific research is further regulated in Section 6 of the NDPA. The NDPA retains most of the current regime, but includes some exceptions from Article 89 of the GDPR and prescribes safeguards which must be ensured according to Article 89 if personal data is processed for scientific, historical or statistical purposes (see section 0).

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? Is it a logical change? Is the supervisory authority involved? If yes, how?

Under the currently valid regime, the authorisation of the EDPI (supervisory authority) is always necessary for processing data permitting identification, if there is no consent of the data subject. The EDPI must check that the processing activities would be in compliance with law and in case of health data also hear the opinion of the ethics committee founded based on law in the corresponding area. The EDPI is not bound by this opinion, but nevertheless has to substantiate diversion from this opinion.

Under the NDPA, it is the respective ethics committee that will conduct the evaluation on whether the processing for scientific research is compliant with legal requirements. Only when such ethics committee is missing will the EDPI take the role of checking the compliance. This change is logical, because it gives more influence to specific ethics committees who have a better understanding of the content of the scientific research and its purposes, while delegating the task to EDPI, who has supervisory power, only in exceptional occasions.

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

Under the NDPA, the processors of sensitive personal data (including health data) no longer have an obligation to appoint a person responsible for data processing (note that this is not connected to the possible obligation to appoint a DPO as prescribed under the GDPR) or registering its processing with the EDPI. Therefore, the process is simplified for the controller.

Estonia has also exercised the right under Article 89(2), whereby member states can permit derogations from the rights of the data subjects under Articles 15,16,18 and 21 of the GDPR so far as such rights are likely to render impossible or seriously impair the achievement of the specific purposes of the scientific research.

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?

Retention of data for further processing is permitted under the currently valid PDPA only if:

a. Data is in coded form; and

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

Partners
EXUS AE (Coordinator), ICCS, KINGSTON, CERTH, Maxeler Tecnologies Limited, UPPSALA UNIVERSITET, UNISR, Time.Lex, EUR, CHS, LOBA, PAGNI, GNUBILA FRANCE, NTU

b. Further processing meets the requirements prescribed for data processing for scientific research.

Decoding and the possibility to decode is permitted only for the needs of additional scientific research or official statistics. However, even then the decoding must be substantiated (see section 0 for the requirements).

Under the NDPA, processing without consent of data subject for research purposes is permitted for pseudonymised (or other similar) form. It is permitted to make the data identifiable only for further processing for scientific, historical or statistical research. Data controller must name the person who has access to the data enabling identification. Therefore, the possibilities for using the data for further processing in the context of scientific research have remained essentially similar.

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?

Health data is collected in HIS. The ethics committee of HIS assesses whether the release of personal data from the HIS for the purposes of scientific research or statistics is necessary and justified. See question 0 above.

The ethics committee of HIS has a code of conduct whereby their general principles of organisation and principles for processing the applications for disclosing the data from HIS for scientific research have been specified. This document is available only in Estonian language at: http://www.e-tervis.ee/images/stories/est/visioonidokumendid/tisek_hea_tava_juhised.pdf

a. Sources of data and their regulation

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

Health data is collected in the national database HIS. The state has also several specific databases, to which data is transferred to digitally via the HIS or other data exchange channel or on paper. Such databases are:

a. Estonian Cancer Registry;

b. Estonian Medical Birth Registry;

c. Estonian Myocardial Infarction Registry;

d. Estonian Tuberculosis Registry;

e. Water and Health Safety Information System;

f. Estonian Cancer Screening Registry;

g. Estonian Communicable Diseases Registry.

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

Partners
EXUS AE (Coordinator), ICCS, KINGSTON, CERTH, Maxeler Tecnologies Limited, UPPSALA UNIVERSITET, UNISR, Time.Lex, EUR, CHS, LOBA, PAGNI, GNUBILA FRANCE, NTU

Access to those registries is granted in the basis of the PDPA and PIA. Access to Water and Health Safety Information System for scientific research purposes is given at the consent of the authorised processor of the database (i.e. the Estonian Health Board).

The controller (University of Tartu) of the Gene Bank (see section 0) may issue to a *genetic researcher* tissue samples, descriptions of DNA or descriptions of state of health from the Gene Bank only in coded form, as a set of data and on the condition that samples or data concerning at least five gene donors are issued at a time. The decision to issue the data is made by the ethics committee of the Gene Bank. Genetic researcher means a natural or legal person or a state or local government agency who performs genetic research.

- **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.

Before commencing the research, the data controller must either appoint a person responsible for the personal data processing or register itself at the EDPI (see section 2 above).

For collecting personal data from the patients researcher needs to obtain the informed consent of the data subject (unless there is another legal basis for such processing). When collecting consent for processing of sensitive personal data, it must be explained to the data subject that the data to be processed is sensitive personal data and the data subject's consent must be obtained at least in a format which can be reproduced in writing.

If the processing is not based on consent, the data may be processed only in coded form. This means that before handing over data for processing it, the data allowing a person to be identified must be substituted by a code. Decoding and the possibility to decode is permitted only for the needs of further scientific research or official statistics. The processor of the personal data must appoint a specific person who has access to the information allowing decoding.

Processing of data concerning a data subject without the person's consent for scientific research or official statistics purposes in a format which enables identification of the data subject is permitted only if, after removal of the data enabling identification, the goals of data processing would not be achievable or achievement thereof would be unreasonably difficult. In such case, the personal data may be processed without the consent only if the person carrying out the scientific research finds that there is a predominant public interest for such processing and the volume of the obligations of the data subject is not changed on the basis of the processed personal data and the rights of the data subject are not excessively damaged in any other manner.

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

In general terms no, except that data controllers no longer have an obligation to appoint a person responsible for data processing (note that this is not connected to the possible obligation to appoint a DPO as prescribed under the GDPR) or registering its processing with the EDPI. Other procedures have been explained in section 4 above.

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

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

Partners
EXUS AE (Coordinator), ICCS, KINGSTON, CERTH, Maxeler Tecnologies Limited, UPPSALA UNIVERSITET, UNISR, Time.Lex, EUR, CHS, LOBA, PAGNI, GNUBILA FRANCE, NTU

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

Under the HSOA, health care providers who have the obligation to maintain confidentiality arising from law, have the right to process personal data required for the provision of a health service, including sensitive personal data, without the permission of the data subject. Conduction or participating in scientific research is not provision of health service. Therefore, the health care providers cannot disclose such data to the researchers unless there is a valid legal basis for such processing (e.g. consent of the data subject or obligation from law).

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

No.

- **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.

Setting up a private database containing health data for research purposes is not regulated under law. Nevertheless, setting up the database is processing of sensitive personal data, which must have a valid legal basis (e.g. consent of the data subject or legal basis from law). Processing of sensitive personal data is currently subject to notification obligation (see section 2 above). There is no obligation to separately notify the supervisory authorities of such private databases as such.

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

Registering/notification obligation of sensitive data processing will be repealed (see section 0). Otherwise the currently planned regulation does not concern the setting up of private databases.

- **PUBLIC DATABASES**

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

Yes, see section a above.

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

The new draft implementation act to the NDPA specifies that the data from the databases listed in section a a.-f. above can be issued in anonymised form for scientific research purposes. In personalised form the data is issued for scientific research (or data subject's consent) by following the regulation under the NDPA for data processing for scientific purposes. This does not apply to Estonian Communicable Diseases Registry and Gene Bank, where the data issued for scientific research purposes is always in a coded form or unidentifiable.

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

Partners
EXUS AE (Coordinator), ICCS, KINGSTON, CERTH, Maxeler Tecnologies Limited, UPPSALA UNIVERSITET, UNISR, Time.Lex, EUR, CHS, LOBA, PAGNI, GNUBILA FRANCE, NTU

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

1. Type 2 diabetes

The AEGLE project uses, after pseudonymising, 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?

If the data has been anonymised (coded) on AEGLE platform, then no prior procedural steps are necessary.

If data is personalised (i.e. it is possible to identify a person) and provided that Estonian law is applicable to the processing, then under current regime the researcher must register processing of sensitive personal data and obtain the consent of the data subject for further processing. Without the consent of data subject, the researcher must obtain the consent of the EDPI for the processing. In latter case the consent of the data subject is not necessary.

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

Similarly to current regime, pseudonymised data can be processed without additional formalities. If the data is being pseudonymised in the process (i.e. researcher is the one who anonymises the data) then consent of the data subject should be obtained for further processing. Prior evaluation of an ethics committee (or EDPI, depending on the circumstances) is necessary if processing is not based on consent (see section 4).

2. Intensive Care Unit (ICU)

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

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?

See section 0.

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

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

Partners
EXUS AE (Coordinator), ICCS, KINGSTON, CERTH, Maxeler Tecnologies Limited, UPPSALA UNIVERSITET, UNISR, Time.Lex, EUR, CHS, LOBA, PAGNI, GNUBILA FRANCE, NTU

See section 0.

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?

See section 0.

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

See section 0.

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

Partners
EXUS AE (Coordinator), ICCS, KINGSTON, CERTH, Maxeler Tecnologies Limited, UPPSALA UNIVERSITET, UNISR, Time.Lex, EUR, CHS, LOBA, PAGNI, GNUBILA FRANCE, NTU

AEGLE

Partners of the AEGLE's Consortium

(COORDINATOR)
EXODUS

Anna Palaiologk

www.exus.co.uk
a.palaiologk@exodussa.com

Greece

EUR (Erasmus Universiteit Rotterdam)

Prof. Jos Aarts, PhD, FACMI
aarts@bmg.eur.nl

Prof. Ken Redekop, PhD
redekop@bmg.eur.nl

www.eur.nl

Netherlands

GNUBILA FRANCE

David Manset

dmanset@gnubila.fr
www.gnubila.fr

France

LOBA

Alexandre Almeida

alexandre@loba.pt
www.loba.pt

Portugal

ICCS (Institute of Communication and Computer Systems)

Prof. Dimitrios Soudris
dsoudris@microlab.ntua.gr

www.iccs.gr

Greece

KINGSTON (Kingston University Higher Education Corporation)

Prof. Barbara Pierscionek, Associate Dean (Research and Enterprise)

b.pierscionek@kingston.ac.uk.
http://sec.kingston.ac.uk

United Kingdom

UPPSALA UNIVERSITY

Richard Rosenquist Brandell, MD, PhD, Professor of Molecular Hematology

richard.rosenquist@igp.uu.se
www.igp.uu.se

Sweden

UNISR (University Vita-Salute San Raffaele)

Paolo Ghia, MD, PhD, Associate Prof. of Internal Medicine

ghia.paolo@hsr.it
www.hsr.it

Italy

UNIVERSITY HOSPITAL OF HERAKLION - PAGNI

Vaporidi Katerina

vaporidi@med.uoc.gr
http://icu.med.uoc.gr

Greece

CHS (Croydon Health Services National Health Service Trust)

John Chang, R&D Director/ Consultant Pediatrician

john.chang@croydonhealth.nhs.uk
www.croydonhealthservices.nhs.uk

United kingdom

TIME.LEX

Prof. Dr. Jos Dumortier

jos.dumortier@timelex.eu
www.timelex.eu

Belgium

CERTH (Centre for Research and Technology Hellas)

Prof. Nicos Maglaveras (PhD Electrical Engineering)

nicmag@med.auth.gr
www.certh.gr

Greece

MAXELER TECHNOLOGIES LIMITED

Tobias Becker

tbecker@maxeler.com
www.maxeler.com

United Kingdom

NOTTINGHAM TRENT UNIVERSITY (NTU)

Barbara Pierscionek

barbara.pierscionek@ntu.ac.uk
https://www.ntu.ac.uk

United Kingdom

This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 644906

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