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

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Contents

I. Overview of the legal framework 3
a. Which laws regulate the processing of health data for research purposes (the current regime, in force till 25 May 2018) 3
b. Revision of the current legal framework under the GDPR 4
c. The national data processing authority 5
II. Transposition of Article 8 (4) of Directive 95/46 6
a. Transposition of Article 8 (4) of Directive 95/46 6
b. The regime applying to the processing of personal data for health research purposes 7
c. Are there additional specific conditions governing the processing of data for scientific research purposes? 9
d. Formalities prior to processing: the general regime under the current framework 11
III. Further processing of health data (for research purposes): the current regime 11
IV. The GDPR's impact on the current regulatory framework for the processing of health data for research purposes 14
a. The impact of the GDPR on the rules applying to processing for research in the field of health 14
b. Modification to the processing authorisation procedure applying to research in the field of health 16
V. Further processing for research purposes under the GDPR 16
VI. Health data sources for research purposes 17
a. Sources of data and their regulation 17
b. Application of the national framework to the AEGLE cases 21
1. Type 2 diabetes 21
2. Intensive Care Unit (ICU) 23
3. Chronic Lymphocytic Leukemia (CLL) 23

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I. Overview of the legal framework

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

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

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

- Personal Data Protection Act (Official Gazette of the Republic of Slovenia, no. 86/04, 113/05, 51/07, 67/07 and 94/07; in Slovenian as *Zakon o varstvu osebnih podatkov,* the *"**Act**"*)

This Act governs the collection and the processing of personal data. The Act was adopted in 2004 and later amended several times. With the amendment in 2005 the 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 (the "**Directive**")[1] was transposed into Slovenian legal system. The Act will undergo further changes with the implementation of the GDPR. The legislative procedure for the adoption of the new data protection law is already under way, but due to resignation of the Slovenian Prime Minister in March 2018 it is unclear whether the new data protection law will be adopted before 25 May 2018.

The unofficial translation of the current Act may be found on the following link: https://www.ip-rs.si/en/legislation/personal-data-protection-act/

- Patient Rights Act (Official Gazette of the Republic of Slovenia, no. 15/08 and 55/17; in Slovenian as *Zakon o pacientovih pravicah*)

The Patient Rights Act governs the rights of patients during the provision of healthcare services and protection of patients' rights. The Health Services Act contains provisions relevant to data processing, in particular provisions concerning: patients' right to access medical files, right to privacy and personal data protection (including scientific research) and protection of professional secrecy.

- Health Services Act (Official Gazette of the Republic of Slovenia, no. 23/05, 15/08, 23/08, 58/08, 77/08, 40/12, 14/13, 88/16 and 64/17; in Slovenian as *Zakon o zdravstveni dejavnosti*)

The Health Services Act governs the provision of healthcare services as well as the interconnection of health organizations and healthcare professionals in chambers and associations. The Health Services Act contains very limited provisions relevant to data processing which relate to confidentiality of health data and health data used for scientific research purposes.

[1] 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.

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- Healthcare Databases Act (Official Gazette of the Republic of Slovenia, no. 65/00 and 47/15)

The Healthcare Databases Act governs the processing of data and databases in the field of healthcare and shared electronic health records ("**eHealth**"; in Slovenian as *eZdravje*), their controllers and data users.

- Criminal Code (Official Gazette of the Republic of Slovenia, no. 50/12, 6/16, 54/15, 38/16 and 27/17; in Slovenian as *Kazenski zakonik*)

The Criminal Code governs criminal responsibility and the associated penalties. In relation to personal data, the Criminal Code contains provision incriminating abuse of personal data. Any offence that falls within the definition of the abuse of personal data is punishable by a monetary fine of up to EUR 360,000 or imprisonment of up to one year. More severe cases of the criminal acts (e.g. if the perpetrator acquires proceeds from criminal act or in cases of criminal acts in relation to sensitive data) are punishable by imprisonment of up to three years. If the perpetrator of the criminal act in question is an official person, the prescribed penalty is imprisonment of up to five years.

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?

In Slovenia, electronic patient record or eHealth[2] system exist, but can be used only for provision of eHealth services, which by electronic means allow the processing of data for the purposes specified in the individual eHealth database (e.g. eReferral & eOrder, ePrescription, eTriage, eCommunication, etc.) or in other words for medical treatment purposes. In accordance with the Article 14.b of the Healthcare Databases Act patient's data available in eHealth is processed in order to enable providers of health services in the Republic of Slovenia and abroad to access patient's data and exchange information for the purpose of provision of healthcare services as well as for the purpose of updating the patient's healthcare data.

Since the law explicitly states the purposes for which the patient's data in the eHealth system can be used it follows that patient's data in the eHealth system cannot be used for research purposes.

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?

To ensure the Slovenian framework's compliance with the data protection package, the Act will be amended. In March 2018, the Ministry of Justice presented to public a Data Protection Act-2 (in Slovenian as *Zakon o varstvu osebnih podatkov*-2 or abbreviated as ZVOP-2; the "**Act Proposal**") which is currently in the Governmental procedure

[2] eHealth is as digitally kept clinical and administrative health information of an individual regarding the entire health care of an individual with required data confidentiality; the eHealth is based on a shared national platform that enables interoperability, the development of a patient summary and exchange of e-documentation.

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and has not yet been presented to the National Assembly. Due to Prime Minister's resignation in March 2018 it is unclear whether the Act Proposal will be adopted before 25 May 2018.

The Act Proposal at the time of writing this study (31 March 2018) probably does not present the final version since it is expected that parliamentary parties will most probably propose certain amendments to the Act Proposal during the legislative procedure before its final version is adopted by the National Assembly.

In any case, the Act Proposal will fully replace the Act.

Act Proposal regulates various topics differently or in more detail than the GDPR, even where the GDPR does not specifically allow for such specifications or restrictions. For example, the Act Proposal specifically regulates direct marketing, which may be regarded as carried out for a legitimate interest according to the recitals of the GDPR despite the fact that GDPR does not allow Member States to adopt more specific or different approach in this area. The Act Proposal also specifically regulates video surveillance (which, following the principle of technological neutrality, is not regulated in the GDPR) where similar considerations apply. Regarding the age applicable to the child's consent in relation to information society services the Act Proposal sets the age limit at 15 years and thus lowering the GDPR's default option of 16 years.

On the other hand, the Act Proposal includes no specific regulation on some issues where pursuant to the terms of the GDPR it could, e.g. on specific limitations for processing of genetic data, biometric data or data concerning health.

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?

Slovenian data protection supervisory authority ("**Information Commissioner**"; in Slovenian as *Informacijski pooblaščenec*) is an autonomous and independent body, established on 31 December 2005 with the Information Commissioner Act (Official Gazette of the Republic of Slovenia no., 113/05 and 51/07; in Slovenian as *Zakon o Informacijskem pooblaščencu*). The Information Commissioner supervises both the protection of personal data, as well as access to public information.

Competencies of the Information Commissioner based on the Information Commissioner Act are:

- deciding on the appeals against the decisions by which another body has refused or dismissed the applicant's request for access, or violated the right to access or re-use public information;
- exercising inspection supervision of the implementation of Act and other regulations which regulate processing and protection of personal data and transfer of personal data outside of Republic of Slovenia;
- deciding as appellate body on individual's complaints when controller of personal data refuses his request for access to data relating to him or request for extract, list, examination, confirmation, information, explanation, transcript or copy in accordance with provisions of the Act;

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- as misdemeanour authority the Information Commissioner supervises implementation of the Information Commissioner Act and the Act.

In accordance with the Patient Rights Act, the Information Commissioner is acting as an appellate, inspection and misdemeanour authority. Information Commissioner acts as an appellate authority on the basis of Article 41 (X), Article 42 (V) and Article 45 (VII) of the Patient Rights Act, when a healthcare provider violates the rights of a patient to acquaint himself with his medical records.

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

The Act Proposal does not change the status of the Information Commissioner, which remains the supervisory authority as is in accordance with the Act. The Information Commissioner still acts as an appellate, inspection and misdemeanour authority in respect of any processing activity of personal data in Slovenia, with the exception of those where this is prevented by the constitutional provisions or the provisions of the GDPR: for example, Information Commissioner must not interfere with the independence of the judiciary or must not conduct inspection procedures in areas where even the National Assembly exceptionally does not exercise them (intelligence and security service).

From the point of legal clarity, the existing provisions or certain new provisions have been emphasised / strengthened, especially in relation to the areas where the Information Commissioner cannot act as a supervisory authority (e.g. if the action of the Information Commissioner would constitute an inappropriate or unconstitutional intervention in relation to the spatial or communications privacy or freedom of expression from the personal data protection point of view).

II. Transposition of Article 8 (4) of Directive 95/46

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

Article 8 (4) of Directive 95/46: "*Subject to the provision of suitable safeguards, Member States may, for reasons of substantial public interest, lay down exemptions in addition to those laid down in paragraph 2 either by national law or by decision of the supervisory authority*."

a. Transposition of Article 8 (4) of Directive 95/46

In Slovenia, data concerning health is a special category of personal data (sensitive data) and as such its processing is prohibited except for specifically listed activities set out by Article 13 of the Act (e.g. if the data subject has given his express consent which should in most cases be written; if processing is necessary for the purposes of carrying out the obligations and specific rights of the controller in the field of employment law; if the processing relates to

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data which are manifestly made public by the data subject or is necessary for the establishment, exercise or defence of legal claims; or when the processing is done for medical purposes).

Activities set out by Article 13 of the Act completely summarize the regime set out by the Article 8 of the Directive including Article 8 (4) of the Directive which is summarized by the Article 13 (8°) of the Act stipulating "*[Sensitive personal data may only be processed in the following cases:] if provided by another act in order to implement the public interest*".

In accordance with the Article 44 (IV) of the Patient Rights Act the use and other processing of patient's health and other personal data outside medical treatment procedures is permitted only with the consent of the patient or the consent of the persons which are entitled to give consent for the patient if the patient is not capable of making decisions for himself. After the patient's death, his immediate family members may give consent, unless the patient has explicitly objected in writing while he was alive.

However, in accordance with Article 44 (VI) of the Patient Rights Act patient's consent for the use and other processing of patient's health and other personal data outside medical treatment procedures is not required for the purposes of epidemiological and other research, education, medical publications or other purposes, provided that the patient's identity is not identifiable.

The above mentioned provision of the Patient Rights Act provides for an exemption to the prohibition of processing of sensitive data and to the otherwise applicable regime that the use and other processing of patient's health and other personal data outside medical treatment procedures is permitted only with patient's consent (or the consent of the persons which are entitled to give consent for the patient if the patient is not capable of making decisions for himself).

Besides the provision of the Article 44 (VI) of the Patient Rights Act also the provision of the Article 54(II) of the Health Services Act stipulates that if patient's health or other personal data are used for scientific research purposes, they must be used in a manner that prevents the identification of the person to whom they relate. This also applies to the publication of the results of scientific research work.

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?

There is no specific regime applying to data processing for research in the field of health purposes however, certain provisions of Act, Health Services Act and Patient Rights Act apply.

In accordance with the Article 17 of the Act personal data may be further processed for historical, statistical and scientific-research purposes provided that personal data are supplied to the data recipient in an anonymised form unless otherwise provided by law or if the individual to whom the personal data relate gave prior written consent for the data to be processed without anonymizing.

Results of processing for the above stated purposes shall be published in an anonymised form, unless otherwise provided by law or if the individual to whom the personal data relate gave written consent for publication in a non-anonymised form.

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Personal data supplied to data recipient in accordance with the above rules shall on completion of processing be destroyed, unless otherwise provided by law. The data recipient shall also without delay after destruction of personal data inform the data controller who supplied him the personal data in writing when and how the personal data were destroyed.

As already explained under point II. A. above, in accordance with the Article 44 (IV) of the Patient Rights Act the use and other processing of patient's health and other personal data outside medical treatment procedures is permitted only with the consent of the patient or the consent of the persons which are entitled to give consent for the patient if the patient is not capable of making decisions for himself. After the patient's death, his immediate family members may give consent, unless the patient has explicitly objected in writing while he was alive.

However, in accordance with Article 44 (VI) of the Patient Rights Act patient's consent for the use and other processing of patient's health and other personal data outside medical treatment procedures is not required for the purposes of epidemiological and other research, education, medical publications or other purposes, provided that the patient's identity is not identifiable.

Similarly also the provision of the Article 54(II) of the Health Services Act stipulates that if patient's health or other personal data is used for scientific research purposes, it must be used in a manner that prevents the identification of the person to whom it relates. This also applies to the publication of the results of scientific research work.

If the research is conducted by the healthcare provider that is collecting the data in question, the anonymisation during the internal research is not necessary – however the published results of the research need to be anonymised.

Until 25 May 2018 each data controller has the obligation to notify the Information Commissioner on each established processing activity and filling system (15 days prior to the start of processing activity).

In accordance with Article 57 of the Health Services Act testing of unverified methods of prevention, detection, treatment and rehabilitation as well as testing of medicinal products and other biomedical research is permitted only with the consent of the Ministry of health and with the written consent of the patient (regarding minors and persons under guardianship the written consent of the parents or guardian is required).

In accordance with the Article 4 of the Rules on the membership, duties, responsibilities and working methods of the Commission for Medical Ethics the National Medical Ethics Committee ("**NMEC**") give consent:

- to the proposals for scientific research projects in the field of health,
- for the testing of unverified methods of prevention and detection of diseases and injuries, treatment and rehabilitation,
- for the testing of medicinal products,
- for carrying out other biomedical research.

All research on human subjects funded by public money must be reviewed for ethical acceptability and approved by the NMEC which includes, among others:

- all biomedical research in the framework of theses for M.Sc. or D.Sc. degrees, as well as students' scientific research,
- all clinical trials of pharmaceutical products.

When consent has not been obtained from the data subject, NMEC has the power to make decisions about when research is justified in the public interest. Where unreasonable effort would be necessary to contact the data

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subjects, the potential risk of damage to the data subject appear remote, and the study is expected to provide important new scientific information, the NMEC may exempt the research proposer from the duty to seek consent.

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

In Slovenia researchers are not exempt from generally applicable data protection provisions, however certain provisions of different acts apply explicitly to the scientific-research purposes as already explained above under II. B.

Usually patient's consent is required for the use and other processing of patient's health and other personal data outside medical treatment procedures, however in accordance with the explicit provision of the the Article 44 (VI) of the Patient Rights Act patient's consent for the use and other processing of patient's health and other personal data outside medical treatment procedures is not required for the purposes of epidemiological and other research, education, medical publications or other purposes, provided that the patient's identity is not identifiable.

However, as explained in the answer to the preceding questions, when consent has not been obtained from the data subject, NMEC has the power to make decisions about when research is justified in the public interest. Where unreasonable effort would be necessary to contact the data subjects, the potential risk of damage to the data subject appear remote, and the study is expected to provide important new scientific information, the NMEC may exempt the research proposer from the duty to seek consent.

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

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

Certain safeguards apply in relation to the processing of patient's health and other personal data outside medical treatment procedures as already explained above under points II. A. and II. B. and which relates to the identification of the patient which health and other personal data are processed for the scientific-research purposes (e.g. patient's identity must not be identifiable when processing his personal data, data in the publication of the results of scientific research work have to be anonymised).

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?

Patient's health and other personal data must be handled in accordance with the professional secrecy principle and the rules governing the protection of personal data. However, according to Article 44 (VI) of the Patient Rights Act, patient's personal data may be transmitted to the recipient of data for the purposes of studies and research in a form that prevents identification of patient's identity.

In accordance with Article 51 (II) of the Health Services Act and Article 45 (I) of the of the Patient Rights Act all persons (alongside healthcare professionals) to whom patient's health data is available due to the nature of their work are bound by the professional secrecy, which means that the recipients of the data for studies and research purposes are also bound by it.

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In accordance with the provision of Article 44 (IV) of the Patient Rights Act the use of patient's health and other personal data outside medical treatment procedures is only allowed with the consent of the patient. In case of a deceased person such consent may be provided by immediate family members unless the patient has explicitly objected in writing while he was alive. However, Article 44 (V) of the Patient Rights Act stipulates that irrespective of the provision of Article 44 (IV) the use of patient's health and other personal data outside medical treatment procedures may be determined by law. This provision is then applied in the provision of the Article 44 (VI) of the Patient Rights Act[3] and which presents a lawful basis for processing of patient's health and other personal data without the consent of the patient. This provision relates to deceased data subjects as well.

Since NMEC gives consent to the proposals for scientific research projects in the field of health it has the power to either require from the research proposer to obtain an express consent from the data subject for processing of personal data or may exempt the research proposer from the duty to seek consent.

There are no specific provisions for minors or persons subject to guardianship in relation to the processing of their health data for the purposes of studies and research and the above mentioned rules apply.

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

Article 19 of the Act provides that if personal data are collected directly from the data subject, he is to be individually informed prior to the processing of:

- the data controller or his representative (personal name, title or official name respectively and address or seat respectively),
- the purpose of the processing of personal data.

If in the view of the special circumstances of processing of personal data there is a need to ensure lawful and fair processing of personal data of the data subject, the data subject is to be individually also informed on the following additional information:

- the data recipient or the type of data recipients of data subject's personal data,
- whether the collection of personal data is compulsory or voluntary and the possible consequences if the individual will not provide data voluntarily,
- the right to access, transcribe, copy, supplement, correct, block and erase personal data that relate to data subject.

The above rules apply also in case where personal data are not collected directly from the data subject to whom they relate.

In accordance with the Article 19 (V) of the Act the above information shall not need to be ensured to data subject if in order to process personal data for historical, statistical or scientific-research purposes this would be impossible or would incur large costs or disproportionate effort or would require a large amount of time, or if the recording or supply of personal data is expressly provided by law.

[3] Article 44 (VI) of the Patient Rights Act: patient's consent for the use and other processing of patient's health and other personal data for the purposes of epidemiological and other research, education, medical publications or other purposes is not required, provided that the patient's identity is not identifiable.

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However, the NMEC insists on information as to anticipated or intended processing of personal data to be given to data subjects, whether or not the data are rendered anonymous.

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?

Article 91 of the Act stipulates that a fine shall be imposed for a misdemeanour on a legal person, sole trader or individual independently performing an activity, if they supply personal data in contravention / do not destroy personal data in accordance / do not publish the results of processing in accordance with Article 17 of the Act (which stipulates that: personal data may be further processed for historical, statistical and scientific-research purposes; in such case it should be supplied in an anonymised form, unless otherwise provided by statute or if the individual to whom the personal data relate gave prior written consent for the data to be processed without anonymising; the data supplied shall on completion of processing be destroyed; the results of processing shall be published in anonymised form, unless otherwise provided by law or unless the individual to whom the personal data relate gave written consent for publication in a non-anonymised form or unless written consent for such publication has been given by immediate family members of the deceased person).

The fines are set in the range from EUR 4,170 to EUR 12,510 for legal persons and from EUR 830 to EUR 2,080 for responsible persons of legal persons and from EUR 200 to EUR 830 for individuals.

The above mentioned fines apply also in case a data subject is not informed on the processing of personal data in accordance with the Article 19 of the Act (as explained above in the answer to the preceding question).

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

Is there a regime requiring the fulfilment of certain conditions prior to any processing activities different from that applicable to research in the field of health? If yes, what does that regime entail?

In Slovenia, any processing of personal data (including sensitive data) is ruled by the general regime for processing of personal data in accordance with the Act.

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

In accordance with the Article 16 of the Act personal data may only be collected for specific and lawful purposes, and may not be further processed in such a manner incompatible with these purposes, unless otherwise provided by law.

As explained above further processing for scientific research is allowed only if the data subject has consented to such processing or if further processing for scientific research is based on the explicit provision of the Article 44 (VI)

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of the Patient Rights Act where the consent of the data subject is not required if certain conditions are met (e.g. data subject is not identifiable, publication of the results of the scientific research are anonymised, etc.).

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

As explained above the notion of further processing is found in Article 16 of the Act.[4] To be lawful, further processing must be compatible with the purposes of processing for which the data was collected. Data collected for a specific and lawful purpose cannot be processed in a manner incompatible with this purpose, unless otherwise provided by law.

However, in accordance with Article 17 (I) of the Act personal data may be further processed for statistical purposes or for scientific or historical research purposes irrespective of the initial purpose of collection of personal data.

In case of further processing of personal data for statistical purposes or for scientific or historical research purposes certain rules apply, such as:

- personal data must be supplied to the data recipient in an anonymised form unless otherwise provided by law or if the individual to whom the personal data relate gave prior written consent for the data to be processed without anonymising (Article 17 (2) of the Act);
- personal data supplied to data recipient shall upon completion of processing be destroyed, unless otherwise provided by law. The data recipient shall also without delay inform the data controller who supplied him the personal data in writing when and how personal data was destroyed;
- the results of the scientific research should be published in anonymised form.

Under current regime (in force until 25 May 2018), besides the above requirements, the controller has the obligation to notify the Information Commissioner on each established processing activity and filling system (15 days prior to the start of processing activity), which applies to further processing for statistical purposes or for scientific or historical research purposes as well.

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

The Act does not provide for specific provision which would regulate scientific research in the field of health purposes. Therefore for all scientific research purposes rules explained in the answer to the preceding question apply.

Besides the above rules the Article 44 (VI) of the Patient Rights Act should be taken into account which allows further processing of patient's health and other personal data without the consent of the data subject for the purpose of epidemiological and other studies, educational purposes and medical publications provided that and the patient's identity is not identifiable.

This provision allows collection of data from patient records. However they need to be processed in a manner that prevents an external researcher to identify whom these data are pertaining to. The data must be collected and processed in a form that does not allow the connection to the patient. If the research is conducted by the healthcare provider that is collecting the data in question, the anonymisation during the internal research is not necessary – however the published results of the research need to be anonymised.

[4] Article 16 of the Act: Personal data may only be collected for specific and lawful purposes, and may not be further processed in such a manner that their processing would be counter to these purposes, unless otherwise provided by law.

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Please note that when issuing the consent to the research proposer regarding the proposals for scientific research projects in the field of health NMEC has the power to require from the research proposer to seek consent from the data subject.

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

In Slovenia, the data subject's rights in relation to further processing of personal data are the same as the general rights of data subjects under the Act.

In accordance with the Article 30 of the Act data subjects have the right to be informed of, among others, the fact that his personal data are being processed, the purposes for collection and processing of personal data, the type of personal data being processed, the data recipients or categories of data recipient, rights of access and correction of personal data etc.

Furthermore, Article 31 of the Act prescribes that the data controller is obliged, in a period no longer than 15 days following such request of the data subject, to:

- enable the data subject an inspection of the database catalogue;
- provide information in an understandable form on the data subject's personal data that is processed and the source of such data;
- provide data subject with an extract of personal data contained in database that relate to data subject;
- provide a list of data recipients to whom personal data were supplied, when, on what basis and for what purpose;
- provide information on the sources on which records contained about the individual in database and on the method of processing;
- provide information on the purpose of processing and the type of personal data being processed;
- explain technical and logical-technical procedures of decision-making, if the controller is performing automated processing of personal data of the data subject.

Under Article 32 of the Act, on the basis of the data subject's request, the data controller has to amend, complement or erase personal data if such data is incorrect, incomplete or outdated or if their processing is not conducted in accordance with the Act.

Irrespective of the data subject's request, the data controller is obliged to amend or delete personal data on his own initiative, if he establishes that that personal data that is processed is incomplete, inaccurate or outdated.[5]

The data subject must be informed on any amendment/erasure described above in a period of 15 days following such amendment/erasure.

Besides the above applicable provisions of law, the NMEC also insists on information as to anticipated or intended processing of personal data to be given to data subjects, whether or not the data are rendered anonymous.

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

[5] Article 33 (V) of the Act: "(4) If the data controller concludes on his own that the personal data is incomplete, inaccurate or not up to date, he shall supplement or correct such data and inform the individual thereof, unless otherwise provided by law."

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There are no specific data subject's rights related to further processing for scientific research purposes, apart from the general rights of data subjects as described in the previous answer.

IV. 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?

In the context of this study, only Articles 8, 10, 12, 79 and 80 of the Act Proposal are particularly relevant. They deal respectively with: lawful basis for processing of personal data and further processing for scientific research, personal data of the deceased persons, sensitive data and processing for scientific research purposes.

Article 8 stipulates that the processing of personal data for a purpose other than that for which it was collected is in the public sector not permissible unless otherwise provided by the Act Proposal or if this provided by another law for the purpose of implementing the objectives referred to in the first paragraph of the Article 23 of the GDPR. (e.g. for scientific or historical research purposes). This does not change the current regime where personal data may be further processed for statistical purposes or for scientific or historical research purposes irrespective of the initial purpose of collection of personal data.

Article 10 regulates personal data of the deceased persons and unless the law provides otherwise, enables the option where the controller may provide information about the deceased person to another person who intends to use this data for scientific or historical research, statistical or archiving purposes provided that the rules set out in the chapter VII of the Act Proposal which governs the processing of personal data for scientific or historical research, statistical or archiving purposes are taken into account.

Article 12 governs the processing of special categories of personal data and summarises the provision of the Article 9 of the GDPR.

Articles 79, 80 and 81 are inserted in the chapter VII of the Act Proposal which governs the processing of personal data for scientific or historical research, statistical or archiving purposes.

Article 79 which implements the Article 9(2)(j) of the GDPR stipulates that further processing for statistical, historical or scientific research purposes is deemed compatible to the purposes of the primary collection and processing of personal data (which also applies for the third party data recipient if he uses personal data for statistical, historical or scientific research purposes) if:

- the data subject to whom the personal data relate gave prior written consent to such processing;
- the data is obtained and further processed in an anonymous form, or

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- so provided by law.

Research organizations and researchers registered in the Database of Research and Development Actors managed by the Slovenian Research Agency may for the statistical, historical or scientific research purposes review or obtain special categories of data (e.g. health data) or other personal data typically in a pseudonymised form if they submit a "demonstration research study" as to demonstrate:

- the actual existence of the research,
- that effective research or its purpose cannot be achieved without processing certain personal data, or this would be linked to disproportionate effort or costs,
- that personal data which are inevitably necessary for the effective conduct of a research cannot be obtained with the consent of the data subject.

The "demonstration research study" must be accompanied by the data protection impact assessment.

Personal data obtained in accordance with the above rules shall upon completion of the processing be destroyed or irreversibly anonymised, unless otherwise provided by law or if the individual has not consented to the further retention of personal data or if this is not relevant to carry out the purpose of the research. The data recipient shall also without delay inform the data controller who supplied him the personal data in writing of when and how personal data was destroyed. The results of the scientific research should be published in anonymised form. The rules explained in this paragraph more or less already applied under the current regime.

Article 80 enables the possibility of processing the addresses for contacting individuals for the purpose of scientific, historical and statistical research. The data controller may, exceptionally, process personal data from a target group of data subjects for the purpose of obtaining consent to process their personal data or in order to obtain additional information or explanations for the above purposes.

The controller may, on the basis of the databases he legally possesses in the context of his lawful activities, and in return for payment, contact data subjects for the purposes of obtaining consent for the needs of others data users / recipients and for the purpose of scientific, historical and statistical research provided that:

- the lawful basis for the processing of personal data is not provided by the law or the consent;
- data recipients with "demonstration research study" demonstrate they will process personal data after obtaining the consent for the purpose of scientific, historical and statistical research.

Personal data supplied or processed under this Article 80 may be processed solely for the purpose of research and should be deleted as soon as they are no longer needed.

Article 81 governs the rules regarding the processing for archiving purposes.

If the Act Proposal will be adopted in its current version then the processing of personal data for scientific or historical research, statistical or archiving purposes will be regulated in much more detail than under the legal framework.

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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?

In Slovenia, processing authorisation procedure does not exists therefore GDPR has not effect to the researches in the field of health in this regard.

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

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

Since in the Act Proposal there is no such derogation it appears that the government did not intend to build upon the opportunity to provide derogations to some rights of data subjects.

V. 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?

The GDPR will be directly applicable therefore the rules provided in the Article 5(1)(b) and the Article 89(1) will be directly applicable as well. Since the Article 17 (I) of the current Act provides that personal data may be further processed for statistical purposes or for scientific or historical research purposes irrespective of the initial purpose of collection of personal data if certain conditions are met, the GDPR will not change the current legal framework in relation to the further processing.

However, the current legal framework in relation to the processing of personal data for scientific or historical research, statistical or archiving purposes will be regulated in much more detail if the Act Proposal will be adopted in its current version as already explained under point IV.A.

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VI. 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?

Public authorities and other entities do not facilitate the availability of health data for research purposes in any specific way.

As already explained above the below rules and requirements have to be taken into account when processing health data for research purposes.

The use and other processing of patient's health and other personal data outside medical treatment procedures is permitted only with the consent of the patient or consent of persons who have the right to consent to medical intervention or medical treatment if the patient is not capable of making decisions for himself. After the patient's death, his immediate family members may give consent, unless the patient has explicitly objected in writing while he was alive.

However, in accordance with Article 44 (VI) of the Patient Rights Act patient's consent for the use and other processing of patient's health and other personal data outside medical treatment procedures is not required for the purposes of epidemiological and other research, education, medical publications or other purposes, provided that the patient's identity is not identifiable.

The Act also stipulates that personal data may be further processed for historical, statistical and scientific-research purposes provided that personal data are supplied to the data recipient in an anonymised form unless otherwise provided by law (e.g. the above mentioned Article 44 (VI) of the Patient Rights Act) or if the individual to whom the personal data relate gave prior written consent for the data to be processed without anonymizing.

a. Sources of data and their regulation

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

- **DIRECT COLLECTION FROM PATIENTS:**

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

Health data or data concerning health is sensitive data and so in principle its processing is prohibited. However, this prohibition does not apply to processing for scientific research purposes under Article 44 (IV) and (VI) of the Patient Rights Act. Such collection and processing must also comply with Article 19 of the Act which stipulates that if personal data are collected directly from the data subject, he is to be individually informed prior to the processing of:

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- the data controller or his representative (personal name, title or official name respectively and address or seat respectively),
- the purpose of the processing of personal data.

If in the view of the special circumstances of processing of personal data there is a need to ensure lawful and fair processing of personal data of the data subject, the data subject is to be individually also informed on the following additional information:

- the data recipient or the type of data recipients of data subject's personal data,
- whether the collection of personal data is compulsory or voluntary and the possible consequences if the individual will not provide data voluntarily,
- the right to access, transcribe, copy, supplement, correct, block and erase personal data that relate to data subject.

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

According to the Act Proposal, all data processing activities in the field of health will be governed by the provisions of the new chapter VII which governs data processing for scientific or historical research, statistical or archiving purposes.

The Article 79 of the Act Proposal stipulates that data controllers and third party data recipients may process personal data for statistical, historical or scientific research purposes if:

- the data subject to whom the personal data relate gave prior written consent to such processing;
- the data is obtained and further processed in an anonymous form, or
- so provided by law.

This means that the collection and processing of data comprising health data would be allowed only under the above conditions. Other requirements with which (if the Act Proposal is adopted) research organizations and researchers registered in the Database of Research and Development Actors will have to comply are already explained above under point IV.A..

Moreover, the data subject would have to be informed under Article 13 and 14 of the GDPR.

- **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.

Collection by health professionals and health institutions for research purposes is possible under certain conditions.

The Act stipulates that personal data may be further processed for historical, statistical and scientific-research purposes provided that personal data are supplied to the data recipient in an anonymised form unless otherwise provided by law (e.g. Article 44 (VI) of the Patient Rights Act) or if the individual to whom the personal data relate gave prior written consent for the data to be processed without anonymizing.

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The use and other processing of patient's health and other personal data outside medical treatment procedures is permitted only with the consent of the patient or consent of persons who have the right to consent to medical intervention or medical treatment if the patient is not capable of making decisions for himself. After the patient's death, his immediate family members may give consent, unless the patient has explicitly objected in writing while he was alive.

However, in accordance with Article 44 (VI) of the Patient Rights Act patient's consent for the use and other processing of patient's health and other personal data outside medical treatment procedures is not required for the purposes of epidemiological and other research, education, medical publications or other purposes, provided that the patient's identity is not identifiable.

Please note that when issuing the consent to the research proposer regarding the proposals for scientific research projects in the field of health NMEC has the power to require from the research proposer to seek consent from the data subject.

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

If the Act Proposal is adopted the existing procedures and rules will change and the current regime will be regulated in more detail.

As already explained above under point IV. A. chapter VII of the Act Proposal will govern the processing of personal data for scientific or historical research, statistical or archiving purposes.

Further processing for statistical, historical or scientific research purposes by data controllers and third party data recipients will be allowed if:

- the data subject to whom the personal data relate gave prior written consent to such processing;
- the data is obtained and further processed in an anonymous form, or
- so provided by law.

Research organizations and researchers registered in the Database of Research and Development Actors managed by the Slovenian Research Agency will be able, for the statistical, historical or scientific research purposes, to review or obtain special categories of data (e.g. health data) or other personal data typically in a pseudonymised form if they will submit a "demonstration research study" as to demonstrate:

- the actual existence of the research,
- that effective research or its purpose cannot be achieved without processing certain personal data, or this would be linked to disproportionate effort or costs,
- that personal data which are inevitably necessary for the effective conduct of a research cannot be obtained with the consent of the data subject.

The "demonstration research study" will have to be accompanied by the data protection impact assessment.

Personal data obtained in accordance with the above rules shall upon completion of the processing be destroyed or irreversibly anonymised, unless otherwise provided by law or if the individual has not consented to the further retention of personal data or if this is not relevant to carry out the purpose of the research. The data recipient shall also without delay inform the data controller who supplied him the personal data in writing when and how personal data was destroyed. The results of the scientific research will have to be published in anonymised form.

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- **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.

While creating a private database containing health data is not prohibited, its legal basis must be carefully applied. Indeed, while the processing of health data is in principle prohibited, it is possible to do so if the data subject has given his/her explicit consent. Until 25 May 2018 such a database must also be notified to the Information Commissioner in accordance with the Article 27 of the Act.

However, if the database is used for scientific research purposes, then the rules already explained above applies (i.e. rules regarding further processing for research purposes, rules regarding the security of personal data used for research).

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

The chapter VII of the Act Proposal will govern the processing of personal data for scientific or historical research, statistical or archiving purposes which will govern such processing activities in much more detail in comparison to the existing regime. Please refer to the answer provided under the point IV. A. above for more detailed explanation of the new regime in processing personal data for scientific or historical research, statistical or archiving purposes.

- **PUBLIC DATABASES**

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

Public healthcare databases are governed by the Healthcare Databases Act which in Appendix 1 lists all public healthcare databases (more than 80 public databases) except for the databases contained in the eHealth system.

Patients' personal data contained in eHealth system can be used for provision of eHealth services only, which by electronic means allow the processing of data for the purposes specified in the individual eHealth database (e.g. eReferral & eOrder, ePrescription, eTriage, eCommunication, etc.) or in other words for medical treatment purposes. In accordance with the Article 14.b of the Healthcare Databases Act patient's data available in eHealth is processed in order to enable providers of health services in the Republic of Slovenia and abroad to access patient's data and exchange information for the purpose of provision of health care services as well as for the purpose of updating the patient's health care data.

Since the law explicitly states the purposes for which the patient's data in the eHealth record can be used it follows that patient's data in the eHealth record cannot be used for research purposes.

In accordance with Article 2 of the Healthcare Databases Act in relation to the other public healthcare databases (excluding eHealth system) the provisions of the Act regarding collection, processing and transfers of personal data contained in these databases apply, unless otherwise provided by the Healthcare Databases Act for individual cases.

As already explained throughout this Study certain rules and requirements have to be taken into account when processing health data for research 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?

Under the revised legal framework the rules applicable to the use of public databases do not effectively change, however the regime explained under point IV. A. above might apply depending on the adoption of the Act Proposal.

b. 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, existing databases with health data collected from patients who expressed their consent to their data being used for research purposes.

Current legal framework:

The operations realised in the AEGLE project qualify as processing for research purposes in the field of health, and therefore the provisions of Act regarding sensitive data and their use for research purposes, provisions contained in the Article 44 and 45 of Patient Rights Act (requirements for processing of patient's data for research purposes and professional secrecy) and provision of Article 51 (II) of the Health Services Act (professional secrecy) apply.

If the data has been collected by healthcare professionals during their activities, then they may transfer the data to researchers in a way that the patient's identity is not identifiable. Researchers will also be bound by professional secrecy for this data.

The data subjects will have to be informed of the further processing of the data as concerns them in accordance with Article 19 (3) and (4). However, if the further processing entails an anonymisation of personal data, then only the identity of the controller and the purpose of the processing must be communicated.

The NMEC may insists on information as to anticipated or intended processing of personal data to be given to data subjects, whether or not the data are rendered anonymous.

Personal data obtained in accordance with the above rules shall upon completion of the processing be destroyed. The data recipient shall also without delay inform the data controller who supplied him the personal data in writing when and how personal data was destroyed. The results of the scientific research should be published in anonymised form.

In accordance with the Article 4 of the Rules on the membership, duties, responsibilities and working methods of the Commission for Medical Ethics the researchers will also need to obtain consent from NMEC:

- in relation to the proposals for scientific research projects in the field of health,
- for the testing of unverified methods of prevention and detection of diseases and injuries, treatment and rehabilitation,

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- for the testing of medicinal products,
- for carrying out other biomedical research.

When consent has not been obtained from the data subject, NMEC has the power to make decisions about when research is justified in the public interest. Where unreasonable effort would be necessary to contact the data subjects, the potential risk of damage to the data subject appear remote, and the study is expected to provide important new scientific information, the NMEC may exempt the research proposer from the duty to seek consent.

Regarding the collection and analysis of the genetic data the view of the NMEC and its practice is to inform the proposers of molecular genetic studies that an approval is only granted for the particular study submitted, and that any new study on the same material is subject to a new review. NMEC requires that the donors of the material are also so informed. In the view of NMEC they must have a choice to give their consent only to the present study (as opposed to all future studies), and in case of any new study to be asked for a new consent.

Revised legal framework:

In accordance with chapter VII of the Proposal Act which governs the processing of personal data for scientific or historical research, statistical or archiving purposes personal data may be further processed for statistical, historical or scientific research purposes if:

- the data subject to whom the personal data relate gave prior written consent to such processing;
- the data is obtained and further processed in an anonymous form, or
- so provided by law.

Research organizations and researchers registered in the Database of Research and Development Actors managed by the Slovenian Research Agency may for the statistical, historical or scientific research purposes review or obtain special categories of data (e.g. health data) or other personal data typically in a pseudonymised form if they submit a “demonstration research study” as to demonstrate:

- the actual existence of the research,
- that effective research or its purpose cannot be achieved without processing certain personal data, or this would be linked to disproportionate effort or costs,
- that personal data which are inevitably necessary for the effective conduct of a research cannot be obtained with the consent of the data subject.

The “demonstration research study” must be accompanied by the data protection impact assessment.

If the data used in the framework of the study is to be transmitted by a health professional, then the recipient is bound by professional secrecy.

The data subject must be informed in conformity with the provisions set out in the GDPR.

Personal data obtained in accordance with the above rules shall upon completion of the processing be destroyed or irreversibly anonymised, unless otherwise provided by law or if the individual has not consented to the further retention of personal data or if this is not relevant to carry out the purpose of the research. The data recipient shall also without delay inform the data controller who supplied him the personal data in writing when and how personal data was destroyed. The results of the scientific research should be published in anonymised form.

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Regarding the actions of NMEC or the consent to be obtained from NMEC the above rules as under the current legal framework will still apply.

2. Intensive Care Unit (ICU)

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

Current legal framework:

The operation realised in the AEGLE project qualifies as processing for research in the field of health purposes, therefore the already explained rules regarding the processing of personal data (including sensitive data) for research purposes apply.

In accordance with the explicit provision of the Article 44 (VI) of the Patient Rights Act patient's consent for the use and other processing of patient's health and other personal data outside medical treatment procedures is not required, among others, for the purposes of epidemiological and other research, education, medical publications or other purposes, provided that the patient's identity is not identifiable.

Researchers will also be bound by professional secrecy for this data.

The data subjects will have to be informed of the further processing of the data as concerns them in accordance with Article 19 (3) and (4). However, if the further processing entails an anonymisation of personal data, then only the identity of the controller and the purpose of the processing must be communicated.

The NMEC may insists on information as to anticipated or intended processing of personal data to be given to data subjects, whether or not the data are rendered anonymous.

Personal data obtained in accordance with the above rules shall upon completion of the processing be destroyed. The data recipient shall also without delay inform the data controller who supplied him the personal data in writing when and how personal data was destroyed. The results of the scientific research should be published in anonymised form.

As in relation to the Type 2 diabetes the competences of NMEC and obligations of the researchers regarding obtainment of the consent are the same for the use and collection of personal data from ICU devices.

Revised legal framework:

Under condition the Act Proposal will be adopted the regime explained under point VI.B.1. apply.

3. Chronic Lymphocytic Leukeamia (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.

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Current legal framework:

The operation realised in the AEGLE project qualifies as processing for research in the field of health purposes, therefore the already explained rules regarding the processing of personal data (including sensitive data) for research purposes apply.

In accordance with the explicit provision of the Article 44 (VI) of the Patient Rights Act patient's consent for the use and other processing of patient's health and other personal data outside medical treatment procedures is not required, among others, for the purposes of epidemiological and other research, education, medical publications or other purposes, provided that the patient's identity is not identifiable.

Researchers will also be bound by professional secrecy for this data.

The data subjects will have to be informed of the further processing of the data as concerns them in accordance with Article 19 (3) and (4). However, if the further processing entails an anonymisation of personal data, then only the identity of the controller and the purpose of the processing must be communicated.

The NMEC may insists on information as to anticipated or intended processing of personal data to be given to data subjects, whether or not the data are rendered anonymous.

Personal data obtained in accordance with the above rules shall upon completion of the processing be destroyed. The data recipient shall also without delay inform the data controller who supplied him the personal data in writing when and how personal data was destroyed. The results of the scientific research should be published in anonymised form.

As in relation to the Type 2 diabetes the competences of NMEC and obligations of the researchers regarding obtainment of the consent are the same for the use and collection of personal data from ICU devices.

Revised legal framework:

Under condition the Act Proposal will be adopted the regime explained under point VI.B.1. apply.

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