

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

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1. Overview of the legal framework

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

a. 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.

- **Constitution of the Slovak Republic**

Legislation on the protection of personal data at national level based on the general personal law protected by state, fundamental rights and freedoms are embodied in the **Constitution of the Slovak Republic**.¹

Pursuant to Art.19(2) and Art.19(3) everyone has the right to protection against unauthorized interference in private and family life and to protection against unauthorized collection, publication, or other misuse of personal data. Art. 16 of the Slovak Constitution states that the inviolability of the person and its privacy is guaranteed whereby we mean the inviolability of privacy in connection with the whole area of intimate personal life and not only in terms of protecting the home and what goes on behind the doors of our house or apartment. However, just a justified concern on personal data breach cannot be considered for violation of this right. Those constitutional rights are implemented in particular into the Data Protection Law.

- **Personal Data Protection Act**

The collection and the processing of personal data in general is laid down in the Act no. 122/2013 Coll. on Personal Data Protection and about Amendment of other Acts (**Personal Data Protection Act**).² Personal Data Protection Act entered into force by the 1 July 2013. Objective of the changing of the act was to completely transpose the Directive of the European Parliament and the European Council 95/46/EC and to implement conclusions and recommendations of Schengen evaluation in the Slovak Republic in the personal data protection area and law analysis from application practice point of view. The current Personal Data Protection Act is complemented by three

¹Constitutional Act no. 460/1992 Coll. Constitution of the Slovak Republic, as amended available on: <https://www.prezident.sk/upload-files/46422.pdf>

² Act no. 122/2013 Coll. on Personal Data Protection and about Amendment of other Acts (Personal Data Protection Act) also in English available: https://www.dataprotection.gov.sk/uouu/sites/default/files/kcfinder/files/Act_122-2013_84-2014_en.pdf



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implementation decrees from 2013 and 2014. Supervision of protected personal data is carried out by the Office of Personal Data Protection of Slovakia, a government body with nationwide coverage.

According to the Art. 13(1) of the Personal Data Protection Act the health data are qualified as the special category of the personal data with the higher level of protection. This provision explicitly lay down, that the processing of personal data concerning health (health data) shall be prohibited.

The current Personal Data Protection Act will be repealed and replaced by directly applicable GDPR and by new Personal Data Protection Act (Act no. 18/2018 Coll. on the protection of personal data).³ The new Personal Data Protection Act will enter into force together with the GDPR on 25 May 2018. The New Personal Data Protection Act largely duplicates the provisions of the GDPR, which as a regulation is directly applicable in Slovakia, but also transposes into the Slovak legal order, the so-called "Police" Directive (European Parliament and Council Regulation (EU) No 2016/680) and also uses the option contained in the GDPR, to define categories of exceptions and derogations from the GDPR in the legal systems EU Member States.

Slovak approach could be assessed as very unusual, mostly because Slovak legislator repeated the text of the Regulation in the text of new Personal Data Protection Act. The focal point revolves around the question of whether the completely transposition of the GDPR was necessary since the GDPR applies directly in all Member States and is directly applicable. Certain ambiguity may arise with respect to the question of which legal regulation to primarily abide by - the wording of the GDPR or the wording of the new Personal Data Protection Act, or some mixed combination of both. Nevertheless, the wording of the draft of the Act seems in most cases to mimic the wording of the GDPR. PDPO argues with provision of Art. 2 a) that stipulates that GDPR does not apply to the processing of personal data in the course of an activity which falls outside the scope of Union law. The leading argument for adoption of similar provisions as in GDPR is, such national provisions are dedicated for those areas and activities which falls outside the scope of Union law. In our case (health, health data and their processing for research purposes) is therefore unambiguously GDPR applicable which take a precedence over the national law.

- **Healthcare Act :**

Healthcare Act (Act no. 576/2004 Z. z. on healthcare, services related to the provision of healthcare and amending certain acts, as amended)⁴ governs the provision of health services. The Healthcare Act governs the healthcare itself and the forms of its provision, defining services related to healthcare, stipulating the rights and obligations in the provision of health care with emphasis on informed consent and health records, defining the procedure after death and outlining the powers of state administration and local government in the area of health care.

This Act defines *inter alia* the rights and obligations of moral and physical persons in the field of healthcare. Also regulates the governmental involvement in the dispensation of health care. Act also contains specific provisions relevant to data processing, in particular provisions concerning medical research.

One whole section of the law is devoted to biomedical research. Here the law is using the Convention on Human Rights and Biomedicine as the basis. It governs the mechanism of research approval, specifying who may not be involved in the research and to what extent a potential research participant must be informed before providing informed consent.

³ In the meantime only Slovak version available.

⁴ Only Slovak version available: <https://www.slov-lex.sk/pravne-predpisy/SK/ZZ/2004/576/20180401#paragraf-24.odsek-4>

Shared electronic health records are indirectly relevant in this context because they can potentially be an important source for health-related research.

The patient's (electronic) medical record (health record):

Medical records are regulated in third part of the Healthcare Act (Art. 18-25). Explicitly consent of data subject (patient) for processing and providing of his/her data from his/her medical record is not required and is included in the consent with provision of the healthcare. Medical record constitute a summary of data (name and surname, anamnesis, extent of the provided health care, identification of the provider, etc.) which is maintained as part of the provision of healthcare. Every item in the medical records must be unambiguously identifiable and therefore the records need to be maintained in such format which enables reliable identification. The written format used in the past is now superseded by a electronic format which will need to comply with electronic signature requirements and other conditions related to data security and data backup. Medical record are recorded in the electronic form within the eHealth Programme in so called "Citizen Health eBook". Citizen Health eBook contains not only the medical (health) record, but also identification data of the patient, electronic prescriptions, electronic medication, data from health insurance company, history of accesses to Citizen Health eBook, records on every particular access and denied accesses. Citizen Health eBook is available for the patient through the National Health Portal using eID card.

Medical records are not subject to ownership and hence cannot be sold or bought, or inherited with medical practice. If the patient portfolio of a practice is being transferred, each patient must express prior consent either in person or through an authorized representative. When the patient changes his/her general practitioner the previous provider of general out-patient care is obliged to hand over medical records (or their copy) demonstrably to the provider taking over within seven days from the request. The previous provider has the right to keep a copy of the records. The law also defines how health records are to be consulted (as this constitutes provision of personal data in terms of personal data protection). In addition to the patient himself/herself the right to see and make notes or copies of the medical records belongs to an authorized third person (e.g. lawful attorney-in-fact). Medical records can also be accessed by other persons by virtue of their profession (medical reviewer of the Health Insurance Company, employees of the Health Market Authority, medical assessors for the purposes of their assessments for social insurance, etc.). There are exceptional cases when the exercise of the right to consult medical records may place the health state of the person in danger (psychiatric patients). In such case the provider is entitled to deny a request to consult the medical records. In as much as the assessment of the possible negative impact of making the medical records available is the responsibility of the provider, the law enables the person in question to exercise the right to consult the medical records by a court order.

Regarding the sharing of medical records, they can be in a limited way shared amongst the medical team treating the patient. Also the patient has to possibility to make available his/her Citizen Health eBook through the National Health Portal also for other specialist treating the patient.

Based on this information, it follows that the shared medical record may only be shared among health professionals when following the treatment prescribed to patients.

- **Penal code (Criminal Code):**

The Criminal code governs criminal responsibility and the associated penalties. Under the Slovak Criminal Code (Act no. 300/2005 Coll. Criminal Code)⁵, according to Art. 374 a person is liable to a term of imprisonment of up to one year if they, without lawful authority, communicates, make accessible or discloses: (i) personal data of another person obtained in connection with the execution of public administration or with the exercise of constitutional rights of a citizen; or (ii) personal data of another person obtained in connection with the execution of his own profession, employment or function, and thus breaches his own obligation prescribed by a generally binding legal regulation.

The offence set out above is punishable by up to two years imprisonment in certain circumstances where there are aggravating factors (causes serious prejudice to the rights of the person concerned, makes it publicly, or acting in a more serious manner).

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 Slovak legal framework's compliance with the data protection package, the current **Personal Data Protection Act** (Act No. 122/2013 Coll. on Personal Data Protection and about Amendment of other Acts), that transposed the Directive 95/46 will be repealed. The former (up to date current) Personal Data Protection Act will be replaced by directly applicable GDPR and for the areas according to Art. 2(a) GDPR (areas and activities which falls outside the scope of Union law) the national law in the form of Personal Data Protection Act was adopted.

New Personal Data Protection Act (Act No. 18/2018 Coll. on Personal Data Protection and about Amendment of other Acts) was on 28 November 2017 already adopted by Slovak Parliament and officially published on 30 January 2018 in the Collection of Laws. The New Personal Data Protection Act replaces the current Personal Data Protection Act. The reason for the adoption of the New Personal Data Protection Act is primarily due to the European reform of the law on the protection of personal data, implemented in particular by the GDPR. New Personal Data Protection Act should enter into force together with the GDPR on 25 May 2018. The New Personal Data Protection Act largely duplicates the provisions of the GDPR, which as a regulation is directly applicable in the Slovakia, but also transposes into the Slovak legal order, the so-called "Police" Directive (European Parliament and Council Regulation (EU) No 2016/680) and also uses the option contained in the GDPR, to define categories of exceptions and derogations from the GDPR in the legal systems EU Member States.

From my point of view, Slovakia has decided to take a very unusual approach. This solution based on repeat the provisions of GDPR in Slovak national law has been heavily criticised by public and by legal experts. The focal point revolves around the question of whether the completely transposition of the GDPR was necessary since the GDPR applies directly in all Member States and is directly applicable. Certain ambiguity may arise with respect to the question of which legal regulation to primarily abide by - the wording of the GDPR or the wording of the new Act, or some mixed combination of both. Nevertheless, the wording of new Personal Data Protection Act seems in most cases to repeat the wording of provisions from GDPR. PDPO argues with provision of Art. 2 a) that stipulates that GDPR does not apply to the processing of personal data in the course of an activity which falls outside the scope of

⁵ English translation available: <http://www.parliament.am/library/Qreakan/slovakia.pdf>



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Union law. The leading argument for adoption of similar provisions as in GDPR is, there are dedicated for those areas and activities which falls outside the scope of Union law.

The key points from new legislation in relation to this study are mostly the exceptions and derogations that are contained in the provisions of Section 78 of the New Personal Data Protection Act.

- Possibility to process personal data for selected purposes without the consent of the data subject:

Without the consent of the data subject, it is possible under Slovak law to process personal data for academic, artistic or literary purposes, or if the processing of personal data is necessary for the informing of the public through mass media and if the personal data is processed by the process or entitled to such business activity. However, such processing must not infringe the right of the data subject for protection of his or her personality or the right to privacy and, according to the explanatory memorandum, the processor must also consider whether the processing operation is indeed necessary.

- Genetic, biometric and health data

The New Personal Data Protection Act gives the processor the possibility to process genetic data, biometric data and health data on the legal basis of a specific law or an international treaty which the Slovak Republic is bound by. This is an authorization for the processor who needs the processing of such personal data for the purpose, for example, of providing healthcare in accordance with special laws.

- Data provided by another natural person

The possibility of obtaining personal data about the data subject from another natural person and their processing in the information system of the processor, is subject to the prior written consent of the data subject. Since this condition is explicitly bound only to the data provided by a natural (not a legal) person, it can be assumed that the provision is intended, inter alia, to protect the personal data of data subjects who have been recommended by other persons knowing them. The aforementioned obligation to obtain prior consent does not apply if, by providing personal data about the data subject into the information system, another individual protects his or her rights or legitimately protected interests, or notifies facts justifying the legal liability of the data subject, or the personal data is processed under a special law subject to specific provisions of the GDPR. A processor who processes such personal data must be able to demonstrate to the Data Protection Office at any time and upon its request that he has obtained it in accordance with this act.

- Processing for archiving purposes, for scientific purposes or for historical research and for statistical purposes

Since these are privileged purposes, which are covered by a derogation from the purpose limitation principle, it is also possible to limit the rights of the data subjects when processing of personal data for these purposes, namely the right of access, the right of rectification, the right of limitation and the right to object, and for the purpose of archiving in the public interest also the right to have another recipient notified and the right for portability pursuant to the GDPR.

c. The national data processing authority

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

In Slovakia, the **Office for Personal Data Protection of the Slovak Republic (PDPO)**⁶ is an independent state authority which performs the supervision of data protection and contributes to the protection of fundamental rights and freedoms with regard to the processing of personal data. PDPO is an independent supervisory authority in Slovakia for protection of personal data in general. PDPO will remain in the position of supervisory authority also after 25 May 2018 (according to the Art. 51 to 59 of GDPR and according to fifth section – articles 80-84 of new Personal Data Protection Act)).

Further very important authority in Slovakia in domain of eHealth, health statistics and partially also for processing health data for research purposes is the **National Health Information Centre (NHIC)**. NHIC is a state-funded organization founded by the Ministry of Health of the Slovak Republic. NHIC performs tasks in the area of informatisation of health service, administration of the National Health Information System, standardisation of health informatics, **health statistics** and provision of library and information services in the field of medical sciences and health service. It administrates national health registries and national health administrative registries as well.

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

The Office for Personal Data Protection (PDPO) will continue to act as the supervisory authority in Slovakia. Its position will remain without significant changes. PDPO will be an independent supervisory authority in Slovakia for protection of personal data. Its task and activities are laid down in the fifth part of new Personal Data Protection Act that regulates the position of PDPO (Art. 80), tasks of PDPO (Art. 81), Head of PDPO (Art. 82) and Deputy Head of PDPO (Art. 83).

Definitely worthy of mentioning are the new obligations to notify breaches of personal data to the PDPO, and to the 'harmed' individual within 72 hours as well as very severe fines. PDPO can impose a fine up to 4 percent of annual global turnover or €20 million for a breach of GDPR.

A new feature of the regulation is certification as acceptable mechanisms for demonstrating compliance with GDPR.

New Personal Data Protection Act also contains provisions regarding the relations and cooperation between PDPO and other European data protection authorities and introduce new obligation of the PDPO to represent Slovakia on the European Data Protection Board.

⁶ Office for Personal Data Protection of the Slovak Republic (PDPO) available on: <https://dataprotection.gov.sk>



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2. Transposition of Article 8.4 of Directive 95/46

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

Art. 8.4 of Directive 95/46: “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.”

Slovak legislator did not insert any additional exemption based on Art 8.4 of Directive 95/46. This provision has not been transposed neither by national law nor by decision of the PDPO (Slovak DPA).

a. 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. This provision was transposed by current Personal Data Protection Act by Art. 13. Data concerning health is a special category of personal data and as such its processing is prohibited by Article 13 of the current Personal Data Protection Act. However, Art. 8(2) of Directive 95/46 transposed by Art.14 of current Personal Data Protection Act lists a series of exemptions to this general prohibition. According to the national law, the prohibition does not apply if, among other grounds (further only ground related to this study):

- the data subject has given his/her express consent, or
- the legal basis for the processing of personal data is based on *lex specialis*, on a legally binding act of the European Union or an international treaty which is binding for the Slovak Republic, or
- when the processing is done for medical purposes: e.g. the processing is performed for the purposes of providing healthcare and effecting public health insurance, provided that these data are processed by a provider of the health care, a health insurance company, a person exercising services related to providing health care or by a person exercising supervision of health care and on his behalf expertly skilled entitled person that is bounded by obligation to maintain secrecy over matters that are part of professional secret and obligation to maintain etiquette of the profession.

Beside the couple of exemptions to general prohibition stated in Art. 8(2) of Directive 95/46 and at the national level in Art. 14 of current Personal Data Protection Act Slovak legislator did not make use of the power granted to Member States in Art. 8(4) and did not insert any additional exemption based on Art 8.4 of Directive 95/46. This provision has not been transposed neither by national law nor by decision of the PDPO (Slovak DPA).

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?

According to the general rule of the current Personal Data Protection Act processing of personal data may be done only by controller in the manner which is pursuant to morality and only pursuant to specified or determined purpose. The purpose of personal data processing itself has to be determined before the processing of personal data starts and the purpose has to be determined unambiguously and concretely and has to be in accordance with the Constitution of the Slovak Republic, constitutional Acts, Acts and international treaties which the Slovak Republic is bounded by. Art. 6(5) of the current Personal Data Protection Act regulates a special exemption for research (in general, not only for health research).

Processing of collected personal data in the course of previously determined purpose and after its termination is admissible in the necessary extent for the historical research, **scientific research** or statistical purposes which shall not be deemed incompatible with the original purpose of processing. The controller shall not use the processed personal data to support measures or actions taken against the data subject and against interests of data subject and as restriction of data subject's rights and freedoms. In the course of personal data processing for the purposes pursuant to the first sentence, the controller shall mark, anonymise them if it allows achieving the purpose of processing and destroy them immediately as they become obsolete.

On one hand the Slovak legal system defines the health data as the special category of personal data and their processing is prohibited. On the other hand this prohibition does not apply if the processing is done for the purposes to provide healthcare. Medical records constitute a summary of data (name and surname, anamnesis, extent of the provided health care, identification of the provider, etc.) which is maintained as part of the provision of healthcare. To conduct a medical record is an integral part of the healthcare provision and therefore there is no requirement to ask for the permission of a patient to process the personal data. What we consider as the paradox biomedical research is defined as a part of the healthcare provision (Art. 2.1 of the Healthcare Act), but explicit prior consent is needed.

In general we distinguish between two main categories of research:

- research involving the human person, and
- research studies or evaluation not involving the human person.

Research involving the human person is defined by the Healthcare Act as a biomedical research and by the Medicinal Product Act (Act no. 362/2011 Coll. on medicinal products and medical devices). This refers to research that is organised and carried out on human beings with a view to the development of biological or medical knowledge. With regard to biomedical research it is very important to mention, that Slovakia in 1998 ratified Convention on Human Rights and Biomedicine⁷ and in 2005 ratified also its Additional Protocol to the Convention

⁷ Convention for the protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine, entered into force on 1 December 1999.

on Human Rights and Biomedicine, concerning Biomedical Research.⁸ According to Art. 7(5) of the Constitution those Conventions are international agreements having precedence over national laws.

Biomedical research is regulated in the Healthcare Act that contains the mechanism of research approval, specifying who may not be involved in the research and to what extent a potential research participant must be informed before providing informed consent.

An opinion of the Ethics Committee (EC) should be sought for any biomedical research project (or for clinical testing – CT) to be conducted in Slovakia. The necessary authorization from the competent state authorities can be granted only after the positive opinion from the EC has been obtained. From the legal point of view, Ethics Committees in Slovakia are established and their function described in Healthcare Act⁹ covers biomedical research in general, including genetic research and in Act No. 140/1998 Coll. on drugs and medical devices (as later amended) and the Ministry's of Health Regulation No. 239/2004 Coll. on clinical investigations and good clinical practice (issued under the Law No. 140/1998) specifically cover clinical trials of medicinal drugs, and of medical devices.

The following types of Ethics Committees (EC) are established in Slovakia:

1. Ethics Committee of the Ministry of Health ('National' EC):

The Ethics Committee of the Ministry of Health is appointed by the Minister of Health according to the provisions of the Healthcare Act as an advisory body on questions of bioethics, including those connected with ethics of biomedical research and clinical trials.

It is to serve to the needs of the Ministry of Health in the first place, but it could also be approached for an opinion/advice/information on bioethical issues by other state institutions (other ministries, the parliament). It is also serves as a consulting body for the 'local' and 'regional' ECs in the SR. The committee represents the SR at the relevant international forums.

The committee only exceptionally performs the ethics review of projects or protocols for a specific research project (when for example, there is no other relevant or responsible ethics committee for the specific project).

The establishment and activities of the committee are governed by its Statutes and Working Procedures issued by the minister of health.

2. (Local) Ethics Committees

(Local) Ethics Committees are established by directors of health care facilities or biomedical research institutions. They are to review protocols of CTs or biomedical research projects planned to be performed in that facility/institution, and to provide a follow up of the research approved.

These ECs may also be required to advice the director of the facility/institution on ethical issues arising from the health care provision by the facility/institution, so to function also as the so-called "clinical ethics committees".

⁸ Additional Protocol to the Convention on Human Rights and Biomedicine, concerning Biomedical Research, entered into force on 1st September 2007.

⁹ Act. No. 576/2004 Coll. on health care (as later amended), only Slovak version available: <https://www.slov-lex.sk/pravne-predpisy/SK/ZZ/2004/576/20180401>



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Health care institutions, however, can establish different ethics committees to deal with 'research' or with 'clinical' ethics.

3. (Regional) Ethics Committees

Regional Ethics Committees are appointed by the regional state authority. Their task is to review and monitor the conduct of multicentre CTs and multicentre biomedical research projects (with an exception of the review of 'local aspects' of CTs/research projects), as well as of CTs/research projects performed on the outpatient basis (via doctors'/specialists' offices).

They also may be required to advise the regional state authority (e. g. the regional state physician) on ethical issues arising from the health care provision in the region.

The second category includes research studies or evaluations not involving the human person. This is health research that does not belong to research involving the human person. In particular, it is research requiring only the re-use of covered personal health data (e. g. from medical records, existing cohorts, or the National System of Health Data). In such case the researchers can be sorted in two categories. If the research is performed by health professionals, then Art. 6(5) of Current Personal Data Protection Act is applicable and no further consent of the patient is needed and such processing is considered to be compatible with determined initial purpose of processing.

But if the researcher intends to obtain the health data either from health professionals or from the data subject (patient), in that case the patient has to be knowledgeable and has to express his/her consent with processing of his/her personal data (health data) for research purposes. This is the case when unanonymised health data are used. From this obligation are exempted the situations when the health data are used for scientific research and are anonymised.

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

Generally applicable data protection provisions and provisions applying to scientific research, it means thus the general regime does not apply are fragmented in the current Personal Data Protection Act. In that case the data controller's obligations can differ from the general regime.

First general rule lays down in Art. 5 Personal Data Protection Act - personal data in Slovakia may be processed only in the manner according to the Personal Data Protection Act and within its borders thus causing no harm to fundamental rights and freedoms of data subjects, mainly to their right to preserve human dignity or other unjustified interference to their right of privacy. Personal data may be processed only by a controller or a processor. The controller processes personal data in the manner which is pursuant to morality and only pursuant to specified or determined purpose.

From those generally applicable data protection provisions are exempted researchers. Beyond the previously determined purpose of processing personal data and also after termination of determined purpose it is admissible in the necessary extent to process the collected personal data for the historical research, **scientific research** or statistical purposes. This cannot be deemed incompatible with the original purpose of processing.

This exemption is only possible under condition when the controller shall not use the processed personal data to support actions or measures taken against the data subject and against interests of data subject and as restriction of data subject's rights and freedoms. Further this exemption is possible under condition when the personal data

processed for the historical research, **scientific research** or statistical purposes, the controller shall mark, anonymise them and destroy them immediately as they become obsolete.

Further general rule for processing of personal data is laid down in Art. 15 of Personal Data Protection Act and consist in various notification obligations of the controller that prepares the processing of personal data to the data subject before obtaining personal data (e.g. to notify on determined purpose, on identification data of controller etc.). The provision of Art 15(3) letter b) governs the exemption of this notification obligation. The data subject does not have to be notified about this information, if the controller processes the personal data for historical or scientific research and development, or for the purposes of statistics. This exemption is applicable under condition when provision of such information is objectively impossible or would involve disproportionate effort.

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?

The text of Article 8 (4) of the Directive requires that the processing of sensitive data, when authorised by the Member States for reasons of significant public interest, are subject to suitable safeguards. Beside the couple of exemptions to general prohibition stated in Art. 8(2) of Directive 95/46 and at the national level in Art. 14 of current Personal Data Protection Act Slovak legislator did not make use of the power granted to Member States in Art. 8(4) and did not insert any additional exemption based on Art 8.4 of Directive 95/46. This provision has not been transposed neither by national law nor by decision of the PDPO (Slovak DPA).

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?

In general according to Art. 22 of current Personal Data Protection Act the controller is obliged to maintain secrecy about the personal data which he process and this obligation is also applicable after termination of the processing of personal data. The entitled person and natural persons, who come into contact with the personal data at the controller's or the processor's place are also obliged to maintain secrecy about the personal data which he comes into contact; he must not use them even for his/her personal needs and he/she must not disclose them, provide them or make them available to anybody without consent of the controller. Professional secrecy obligation also applies after termination of the function of the entitled person or after termination of his employment relationship, civil service employment relationship, service employment relationship or similar labour relationship. Professional secrecy obligation does not apply if it is necessary for fulfilment of duties of courts or law enforcement agencies pursuant to special Act in respect and in the communication with the PDPO in the course of fulfilment of its tasks.

Personal data concerning health is protected by professional secrecy.¹⁰ Every person who process or provide data from medical record or obtained personal data concerning health has to keep secrecy. Health care professionals

¹⁰ Art. 18(3) and Art. 49 Healthcare Act.

who provide healthcare may transmit such data, with special care and under conditions laid down in Healthcare Act, but only to the healthcare professionals (specialist). But, as set out earlier, the recipient of the data (specialist) is subject to professional secrecy obligations too.

Art. 12(6) of current Personal Data Protection Act concerns the data of minors, or persons under guardianship, especially provisions for expressing consent of data subject who is minor or subject to guardianship. This provision is regulated as following: “if the data subject does not enjoy full legal capacity, a consent required under this Act may be provided by his legal representative”. This is a general provision for general expressing of consent of the data subject. For minors and persons under guardianship is in place also the exemption from prohibition of processing of health data (as a special category of personal data) under following condition: “the prohibition relating to the processing of special categories of personal data shall not apply if the processing is necessary for protection of vital interests of the data subject or another natural person if the data subject does not have a legal capacity or is physically unable to issue a written consent and a consent of his legal representative cannot be obtained”.

Specific provision for deceased data subjects is laid down in Art. 12(7) of current Personal Data Protection Act in a way, that if any consent of data subject according to this Act is required in name of deceased data subject the consent may to be provided by his close person (parent, descendant, sibling, husband or other person in family- or similar relation). Such consent shall not be valid if any close person expresses his/her disagreement in writing.

Above were mentioned specific provisions concerning deceased data subject and specific provisions for minors in relation to processing of personal data (health data) if research not involving the human person is realised (research studies or evaluation not involving the human person).

If the second type of health research is realised (research involving the human person – so called biomedical research) then specific provisions in relation to deceased person or minor are the subject of Healthcare Act. Biomedical research is regulated in the Healthcare Act that contains the mechanism of research approval, specifying who may not be involved in the research and to what extent a potential research participant must be informed before providing informed consent.

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

If the controller did not obtain the data subject’s personal data directly from the data subject Art. 15(2) of current Personal Data Protection Act is applicable. This provision regulates the obligation to notify the data subject without undue delay but at the latest before providing them for the first time to the third party about on:

- identification data of the controller and controller’s representative,
- identification data of the processor,
- purpose of the personal data processing,
- additional information if they are needed with regard to special circumstances in which the personal data are being obtained to ensure legal processing mainly
 - o advice on the possibility to decide on processing of the obtained personal data,
 - o list of personal data,

- third parties, provided that it is expected or clear that personal data will be provided to them,
- group of recipients, provided that it is expected or clear that personal data will be made available to them,
- form of making public, provided that personal data shall be made public,
- third countries, provided that it is expected or clear that personal data will be transmitted to these countries, advice on the data subject's rights.

Slovak legislation contains specific exemptions for researchers from the general obligations to inform data subject. Such an exemption is laid down in Art. 15(3) and allows, that data subject does not have to be notified about the information under Art. 15(2) if the controller processes personal data for historical or scientific research and development or for the purposes of statistics. This exemption is not automatically applicable, but only under condition if provision of such information is objectively impossible or would involve disproportionate effort.

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?

Slovak legislation does not contain any specific penalties explicitly if the conditions for processing for scientific research in the field of health purposes are not respected.

But in general any breach of the obligation laid down in the current Personal Data Protection Act would lead the PDPO to impose sanction. Sanctions for violation of the obligation resulting from Act are either a fine or a disciplinary fine (e.g. violation of the obligations to inform data subject according to Art.15 may impose a fine in the amount from € 1.000 to € 50.000 or to everyone who fail to fulfil obligation to maintain secrecy about the personal data may impose a fine in the amount from € 150 to € 2.000.

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 general personal data may be processed only by the controller or the processor. Personal data may be processed only in the manner pursuant to Personal Data Protection Act and within its borders thus causing no harm to fundamental rights and freedoms of data subjects, mainly to their right to preserve human dignity or other unjustified interference to their right of privacy.

Personal data may be processed solely by the controller. To maintain personal data protection the controller is obliged mainly to follow obligations set by the Personal data Protection Act. Prior to processing of personal data it is necessary mainly to undertake following actions and measures:

- determine who is the controller, eventually the processor and determine their mutual relationship via written agreement (Art. 8),

- to determine the purpose of personal data processing provided personal data processing is not carried out pursuant to a special act,
- determine the conditions (means and manners) of personal data processing,
- determine the list of personal data provided personal data processing is not carried out pursuant to a special act,
- abide basic principles of personal data obtaining and processing (Art. 6),
- obtain data subject's consent for personal data processing provided that the Act does not state that personal data may be processed without the consent of the data subject (Art. 10 and 11),
- fulfil obligation to provide information to data subject before obtaining personal data (Art. 15(1) to (3)),
- elaborate appropriate safeguards and security documentation (Art. 19 and 20),
- instruct entitled persons (Art. 21),
- maintain obligation to secrecy (Art. 22),
- abide requirements and relevant obligations for designation of the data protection officer provided that the controller chooses to designate the data protection officer for the execution of personal data processing surveillance (Art. 23 to 26),
- notify the filing systems, submit the filing systems for special registration and keep records of them (Art. 33 to 44),
- provide cooperation to the PDPO in the course of executing its tasks pursuant to the Act.

The controller is obliged to abide particular obligations during the whole course of personal data processing pursuant to conditions of processing.

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

As seen above, the further use of personal data is particularly relevant for scientific research. Indeed, the second of the two main categories of scientific research in the field of health is scientific research not involving the human person. This used to be interpreted notably as research requiring further use of personal data (concerning health).

In general, personal data have to be always collected for specified, explicit and legitimate purposes and may not be further processed in a way incompatible with those purposes. Further processing of data for scientific research purposes will not be considered as incompatible provided and the further processing of data for research is exempted from this general rule and may be further processed also after the termination of the specified purpose of processing.

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

The notion of 'further processing' is regulated in Art. 6 of the Personal Data Protection Act.

In general the controller processes personal data pursuant to Art. 9 Personal Data Protection Act, in the manner which is pursuant to morality and only pursuant to specified or determined purpose. Prior the processing the controller has to follow obligation laid down in Art. 6(2). The controller cannot process collected personal data pursuant to a different purpose that is incompatible with the original purpose of the processing.

Therefore, to be lawful, further processing must be compatible with the purpose of the processing for which the data was collected. Indeed, data is collected for a determined purpose, and cannot be processed in a manner incompatible with this purpose.

However, further processing of data for statistical purposes or for scientific or historical research purposes shall be deemed compatible with the initial purpose of processing, general principles and procedures have to be respected (e.g. the obligation of the data controller, obligation to inform data subject if personal data that has not been collected from the data subject). These are the required conditions for it to be presumed to be compatible with the purpose of the initial processing.

Sixth section of Personal Data Protection Act deals with formalities prior to processing, which is mainly the notification of information systems processing the personal data. Information systems, in which personal data are processed by fully or partially automated means of processing have to be only notified to PDPO. The controller have to notify his/her information system before personal data processing and the notification may be carried out via electronic application form.

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

Art. 6(5) of the Personal Data Protection Act¹¹ deals with processing of personal data for historical research, scientific research or statistical purposes (in general) and contains also specific provision concerning further processing of personal data for historical research, scientific research or statistical purposes (processing of collected data after termination of determined purpose). There is no special mention or reference on processing of personal data for scientific research in the field of health.

Such processing will not be deemed incompatible with the original purpose of processing. This is possible only under condition if the controller shall mark those personal data and will anonymise them (if it allows achieving the purpose of processing and destroy them immediately as they become obsolete). Such anonymous personal data does not contain information enabling direct identification of patient (data subject). If the purpose of processing is cannot be

¹¹Art. 6 (5) Personal Data Protection Act: Processing of collected personal data in the course of previously determined purpose and after its termination is admissible in the necessary extent for the historical research, scientific research or statistical purposes which shall not be deemed incompatible with the original purpose of processing. The controller shall not use the processed personal data to support measures or actions taken against the data subject and against interests of data subject and as restriction of data subject's rights and freedoms. In the course of personal data processing for the purposes pursuant to the first sentence, the controller shall mark, anonymise them if it allows achieving the purpose of processing and destroy them immediately as they become obsolete.

achieved by anonymous data and such processing is not sufficient to achieve a goals of research, then he/she can process personal data in unanonymised form, but prior consent of data subject (patient) is needed.

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

The rights of data subject when it comes to further processing are identical to those have controller prior to processing of personal data in general.

If the controller did not obtain the data subject's personal data directly from the data subject Art. 15(2) of current Personal Data Protection Act is applicable. This provision regulates the obligation to notify the data subject without undue delay but at the latest before providing them for the first time to the third party about on:

- identification data of the controller and controller's representative,
- identification data of the processor,
- purpose of the personal data processing,
- additional information if they are needed with regard to special circumstances in which the personal data are being obtained to ensure legal processing mainly
 - o advice on the possibility to decide on processing of the obtained personal data,
 - o list of personal data,
 - o third parties, provided that it is expected or clear that personal data will be provided to them,
 - o group of recipients, provided that it is expected or clear that personal data will be made available to them,
 - o form of making public, provided that personal data shall be made public,
 - o third countries, provided that it is expected or clear that personal data will be transmitted to these countries, advice on the data subject's rights.

Slovak legislation contains specific exemptions for researchers from the general obligations to inform data subject. Such an exemption is laid down in Art. 15(3) and allows, that data subject does not have to be notified about the information under Art. 15(2) if the controller processes personal data for historical or scientific research and development or for the purposes of statistics. This exemption is not automatically applicable, but only under condition if provision of such information is objectively impossible or would involve disproportionate effort.

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

The provisions governing the obligation to inform the data subject are, as noted earlier, derogated to scientific research by Article 15 (3)(d). The controller does not have an obligation to notify to data subject if he/she processes personal data for historical or scientific research and development or for the purposes of statistics. Derogation clause is applicable under condition, if provision of such information is objectively impossible or would involve disproportionate effort

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?

In the context of this study, Art. 9(2)(j) of GDPR is directly applicable in Slovakia. However also previous mentioned New Personal Data Protection Act was adopted, that absolutely unlogically repeat the provision of Art. 9(2)(j) of GDPR. In general the processing of health data as a special category of personal data is prohibited. Derogation from this prohibition is formulated in Art. 9(2)(j) of GDPR and was repeated in Art. 16(2)(k) of New Personal Data Protection Act. Prohibition shall not apply if processing is necessary for archiving purposes, scientific or historical research purposes or statistical purposes according to Personal Data Protection Act, special Act or binding international treaty and which shall be proportionate to the aim pursued, respect the essence of the right to data protection and provide for suitable and specific measures to safeguard the fundamental rights and the interests of the data subject. In this context I consider it desirable to mention again the fact that Slovakia has decided to take an unusual approach. Slovakia created a completely new Personal Data Protection Act. The focal point revolves around the question of whether the completely transposition of the GDPR was necessary since the GDPR applies directly in all Member States and is directly applicable. Certain ambiguity may arise with respect to the question of which legal regulation to primarily abide by - the wording of the GDPR or the wording of the new Act, or some mixed combination of both. Nevertheless, the wording of the draft of the Act seems in most cases to mimic the wording of the GDPR and repeat its provisions. PDPO argues with provision of Art. 2 a) that stipulates that GDPR does not apply to the processing of personal data in the course of an activity which falls outside the scope of Union law. The leading argument for adoption of similar provisions as in GDPR is, there are dedicated for those areas and activities which falls outside the scope of Union law. This legislator approach will for sure in the future cause many application problems.

Processing of personal data for archiving purposes, for scientific purposes or for historical research and for statistical purposes are so called privileged purposes, which are covered by a derogation clause from following principles and rights:

- from the purpose limitation principle (Art. 7 New Personal Data Protection Act),
- from the storage limitation principle (Art. 10 New Personal Data Protection Act),
- from the right to erasure (right to be forgotten – Art. 23(1) New Personal Data Protection Act),
- from the right to object (Art. 27(1) New Personal Data Protection Act).

In all abovementioned derogation examples are necessary to provide the data subject for suitable and specific measures to safeguard his/her fundamental rights and the interests. According to Art. 78(8) of the New Personal Data Protection Act processing for archiving purposes in the public interest, scientific or historical research purposes or statistical purposes, shall be subject to appropriate safeguards. 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 and data pseudonymisation.

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

Once the controller has made a data protection impact assessment, and the results indicate high risks in the absence of measures taken to limit such risks, then the controller will consult the competent supervisory authority.¹² The Authority can take action within an eight week time period. However, Article 36 (5) of the GDPR leaves the opportunity to the Member States to further regulate this issue for processing carried out in the public interest, in particular for social protection and public health. The Slovak law did not take up this opportunity.

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

Not applicable.

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.

If personal data are processed for scientific or historical research purposes or statistical purposes, Art. 78(9) of New Personal Data Protection Act explicitly states that the rights of the data subject from Articles 21, 22, 24 and 27 of New Personal Data Protection Act and from Articles 15, 16, 18 and 21 of GDPR may be restricted by special law or by international treaty the Slovak Republic is bounded by. Those restriction are possible only under conditions and safeguards referred to in Art. 89(1) of GDPR and 78(8) of New Personal data Protection Act and in so far as such rights are likely to render impossible or seriously impair the achievement of the specific purposes, and such derogations are necessary for the fulfilment of those purposes.

¹² Article 35 and 36 GDPR.

5. Further processing for research purposes under the GDPR

The notion of further processing under the GDPR:

Further processing can be defined as “the processing of personal data for purposes other than those for which the personal data has been initially collected”. Further processing is allowed only when its purpose is compatible with the purpose for which the data has been initially collected. Further processing for a compatible purpose of personal data is possible using the same legal basis as the one used for the initial processing. For example, if personal data is initially processed based on the data subject’s consent, then further processing for a compatible purpose is possible on the same legal basis. It is, in other words, not required to contact the data subject again for a new consent authorising the further processing of the same data.

How to measure the compatibility of purpose of the further processing:

Further processing for a purpose other than that for which the personal data has been collected is governed by Article 6 (4) of the GDPR. In particular this article tries to address how to measure whether or not the purpose of the further processing is “compatible”. This is particularly relevant to big data analytics. Article 6 (4) establishes a test to measure such compatibility.

Where this processing is not based on the data subject’s consent, or EU or Member State law, but on another legal ground, the controller will ascertain the compatibility of the processing’s purpose with the initial purpose stated during the data collection. To do so the controller will take several elements into account, in particular: any link between the initial purpose and the further processing purpose, the context of the collection and the relation between the data subject and the controller, the nature of the data, in particular if it is considered to be sensitive data under Article 9 of the GDPR. The controller will also consider the possible consequence of further processing for the data subject and the existence of appropriate safeguards. If the result of the test is positive for the controller, and shows none of the elements have been significantly altered to make the further processing unfair or illicit, no further legal basis is necessary for the further processing. If this is not the case, then the further processing will have to rely on a separate legal basis.

If this test is successfully met, then the further processing is possible. However, it will be up to the data controller to demonstrate the compatibility of the purposes.

Identical provision has been adopted within New Personal Data Protection Act (Art. 13.3).

The particularities of scientific research: a presumption of purpose compatibility

However, the processing for scientific research purpose is an exception. Indeed, under Article 5 (1) (b) of the GDPR the compatibility of the processing purpose of further processing with the initial purpose of the collection is presumed under Article 89 (1). Here the GDPR establishes a presumption of compatibility of purposes for scientific research purposes. The reasoning behind this exception can be easily imagined. Scientific research is very often based on existing data, this is why allowing the processing of personal for different (if not incompatible) purposes is fundamental for scientific research.

This assumption made for the benefit of scientific research is linked to the derogation of the principle of data minimisation for scientific research purposes. However, this presumption is limited by some requirements, which are set out in Article 89(1) of the GDPR: the appropriate safeguards for the data subject’s rights and freedoms, and

ensured technical and organisational measures, such as pseudonymisation. Although a different scenario would require different technical and organisational measures to ensure the safeguards for the data subject's rights and freedoms. This is clearly indicated in recital 156 of the GDPR: "The further processing of personal data for (...) scientific (...) research purposes (...) is to be carried out when the controller has assessed the feasibility to fulfil those purposes by processing data which does not permit or no longer permits the identification of data subjects, provided that appropriate safeguards exist (such as, for instance, pseudonymisation of the data)."

Additionally, further processing of personal data is connected to the principle of storage limitation (Article 5(1)(e) of the GDPR), as it also constitutes a derogation to that principle, "personal data may be stored for longer periods insofar as the personal data will be processed solely for archiving purposes in the public interest, scientific or historical research purposes or statistical purposes in accordance with Article 89(1) subject to implementation of the appropriate technical and organisational measures required by this Regulation in order to safeguard the rights and freedoms of the data subject".

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

Because the former Personal Data Protection Act from the reasons mentioned above will be repealed on 25 May 2018, the rules set out by the GDPR will be directly applicable in Slovakia.

6. Health data sources for research purposes

a. Sources of data and their regulation

Does your national framework contain specific provisions for anonymised or pseudonymised health data?

Art. 4(3)(i) of former Personal Data Protection Act defines anonymised data as a personal data adjusted in such manner that it cannot be matched with the concerned data subject.

Further the current legal framework mentions the notion "anonymisation" in the provision of the Art. 6 (5) of the Personal Data Protection Act in relation with further processing of personal data for scientific or historical research or for statistical purposes. The method how should the controller the collected and processed personal data anonymise is not further detailed and Slovak national framework does not contain specific provision for anonymised or pseudonymised data.

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 (Art. 13 Personal Data Protection Act). However, this prohibition does not apply when the data subject gave a written or other credibly provable consent to their processing. When a researcher intends to collect health data directly from individuals, such collection and processing must also comply the rules which states, that the data subject or the person from whom the data was collected are to be individually informed, prior to the processing, of: the nature of the information transmitted, the purpose of the processing, the natural or legal person to whom the data is addressed, his/her right of access and rectification, his/her right to object in specific cases, and the controller's obligation to obtain his/her consent. Consent of individuals has to be expressed in a written form or in other credibly provable form.

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 the view of the implementation of the GDPR Slovakia, the former Personal Data Protection Act will be repealed and replaced by new Personal Data Protection Act (Act no. 18/2018 Coll. on the protection of personal data). New Personal Data Protection Act will enter into force together with the GDPR on 25 May 2018. The New Personal Data Protection Act largely duplicates the provisions of the GDPR. GDPR as a regulation is directly applicable in Slovakia, but also transposes into the Slovak legal order, the so-called "Police" Directive (European Parliament and Council Regulation (EU) No 2016/680) and also uses the option contained in the GDPR, to define categories of exceptions and derogations from the GDPR in the legal systems EU Member States. This solution based on repeat the provisions of GDPR in Slovak national law has been heavily criticized by public and by legal experts. New Personal Data Protection Act introduces the new institutes, the procedural rules and the status of the supervisory authority over the personal data protection. New legislation will also reflect the experience of the Slovak Office for Personal Data Protection related to problems of and violation of current law on personal data protection.

Processing of personal data for archiving purposes, for scientific purposes or for historical research and for statistical purposes are so called privileged purposes, which are covered by a derogation clause from following principles and rights:

- from the purpose limitation principle,¹³
- from the storage limitation principle,¹⁴

¹³ Art. 7 New Personal Data Protection Act: "Personal data shall be collected for specified, explicit and legitimate purposes and not further processed in a manner that is incompatible with those purposes; further processing for archiving purposes in the public interest, scientific or historical research purposes or statistical purposes shall, not be considered to be incompatible with the initial purposes under condition the appropriate safeguard of data subject according to Art. 78(8) are guaranteed".

¹⁴ Art. 10 New Personal Data Protection Act: "Personal data shall be kept in a form which permits identification of data subjects for no longer than is necessary for the purposes for which the personal data are processed; personal data may be stored for longer periods insofar as the personal data will be processed solely for archiving purposes in the public interest, scientific or historical research purposes or statistical purposes in accordance with Article 78(8)."

- from the right to erasure (right to be forgotten),¹⁵
- from the right to object.¹⁶

In all abovementioned derogation examples are necessary to provide the data subject for suitable and specific measures to safeguard his/her fundamental rights and the interests. According to Art. 78(8) of the New Personal Data Protection Act processing for archiving purposes in the public interest, scientific or historical research purposes or statistical purposes, shall be subject to appropriate safeguards. 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 and data pseudonymisation.

It is also possible to limit the rights of the data subjects when processing of personal data for these purposes, namely the right of access, the right of rectification and the right of limitation and for the purpose of archiving in the public interest also the right to have another recipient notified and the right for portability pursuant to the GDPR.

Further exemption relates to the prohibition of special categories of personal data (including the data concerning health – health data). New regulation explicitly derogates the prohibition of health data if processing is necessary for archiving purposes in the public interest, scientific or historical research purposes or statistical purposes. Such processing shall be proportionate to the aim pursued, respect the essence of the right to data protection and provide for suitable and specific measures to safeguard the fundamental rights and the interests of the data subject.

Further new regulation explicitly derogates the prohibition of health data processing, if processing is necessary for providing healthcare and effecting public health insurance, provided that these data are processed by a provider of the healthcare, a health insurance company, a person exercising services related to providing healthcare or by a person exercising supervision of healthcare and on his behalf expertly skilled entitled person that is bounded by obligation to maintain secrecy over matters that are part of professional secret and obligation to maintain etiquette of the profession.

Therefore, data processing of personal data for example for study or for research purposes by health professionals, which they have gathered for medical purpose falls, under the data processing general regime set by the GDPR and under New Personal Data Protection Act.

For the collection of personal data concerning health by researchers that are not also acting in the capacity of medical practitioners, is abovementioned Art. 78(8) New Personal Data Protection Act applicable. This means that the collection and processing of data comprising health data would be allowed only if it is justified by the public

¹⁵ Art. 23(1) New Personal Data Protection Act: „The data subject shall have the right to obtain from the controller the erasure of personal data concerning him or her without undue delay“. According to Art 23(4) letter d) this provision „shall not apply to the extent that processing is necessary for archiving purposes in the public interest, scientific or historical research purposes or statistical purposes in accordance with Art.78(8) in so far as the right referred to in paragraph 1 is likely to render impossible or seriously impair the achievement of the objectives of that processing.“

¹⁶ Art. 27(1) New Personal Data Protection Act: „The data subject shall have the right to object, on grounds relating to his or her particular situation, at any time to processing of personal data concerning him or her. The controller shall no longer process the personal data unless the controller demonstrates compelling legitimate grounds for the processing which override the interests, rights and freedoms of the data subject or for the establishment, exercise or defence of legal claims.“ Art. 27(5): „Where personal data are processed for scientific or historical research purposes or statistical purposes pursuant to Art. 78(8), the data subject, on grounds relating to his or her particular situation, shall have the right to object to processing of personal data concerning him or her, unless the processing is necessary for the performance of a task carried out for reasons of public interest.“

interest and only if appropriate safeguards shall ensure that technical and organisational measures are in place in particular in order to ensure respect for the principle of data minimisation and data pseudonymisation.

Moreover, the data subject would have to be informed under Article 13 and 14 of the GDPR.¹⁷ Additionally, if the research requires an identifiable biological sample, then the data subject's informed and express consent is necessary, and must be obtained prior to the processing.¹⁸

- **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 of health data by health professionals and health institutions for research purposes is possible under certain conditions.¹⁹ According to the Art.14 of the current Personal Data Protection Act, the health professionals may process health data for the purposes of providing healthcare and effecting public health insurance. This is a purpose of processing determined by legal basis and explicitly laid down in law. Out of this legally determined purpose, the health professionals may process the collected personal data in the course and after its termination (so called further processing) also for the historical research, scientific research or statistical purposes. In those cases such processing shall not be deemed incompatible with the original purpose of processing. But the health professional (controller) shall mark those personal data and has to anonymise them (if it allows achieving the purpose of processing and destroy them immediately as they become obsolete). Such anonymous health data does not contain information enabling direct identification of patient (data subject).

Otherwise if the processing of anonymous health data is not sufficient for researcher and need to process personal data in unanonymised form, prior consent of data subject (patient) is needed.

Data collection from health institutions can be active (as mentioned above), or researcher can have an access to the database of the National Health Information Centre (NHIC).²⁰ The information collected by the health care establishment and forwarded to NHIC is summarised and de-identified, so that it does not contain information enabling direct identification. NHIC collects and processes data stored in the following registries that are defined as National Health Registers:

- National Registry of Electronic Health Records,

¹⁷ Art. 19 and 20 New Personal Data Protection Act.

¹⁸ Art. 13 New Personal Data Protection Act: Processing of personal data has to be lawfulness in a way that the data subject has given consent to the processing of his or her personal data. Consent of the data subject has to be freely given, specific, informed and unambiguous indication of the data subject's wishes by which he or she, by a statement or by a clear affirmative action, signifies agreement to the processing of personal data relating to him or her.

¹⁹ Art. 6(5) current Personal Data Protection Act.

²⁰ National Health Information Centre (NHIC) is a provider of national health registries. National health registries are health information systems, the primary role of which is to collect, process and analyse data on newly diagnosed diseases occurring on a large-scale or those which are socially significant in the population of the Slovak Republic for the given year (incidence). More information available on : <http://www.nczisk.sk/en>

- National Cancer Registry,
- National Diabetes Mellitus Registry,
- National Congenital Disease Registry,
- National Cardiovascular Registry,
- National Registry of Neurological Disorders,
- National Registry of Chronic Pulmonary Diseases,
- National Registry of Persons with Injury Requiring Inpatient Healthcare,
- National Registry of Persons Suspected of Being Neglected, Abused and on Victims of Violence,
- National Registry of Patients with Inflammatory Rheumatic Diseases,
- National Tuberculosis Registry.

NHIC provides so called National Health Administrative Registries, that contain data on health care providers and health care workers that are following:

- National Registry of Health Workers,
- National Registry of Health Care Providers,
- National Registry of Drug Handling Organizations.

The purpose of data collection and their processing within national health administrative registries is: database management; fulfilment of identification, registration, integration, information and statistical function of registries at both national and international level; creation and evaluation of statistical outputs; issuance and use of electronic health professional cards.

NHIC collects and processes selected data on health status of a population, on network and activities of health care providers and other organisations, on health workforce, medical equipment as well as on economy of health service including health care funding provided on the basis of health insurance, etc. NHIC performs tasks and activities related to the administration, updating and processing of national health registries data.

The obtained and processed data are subsequently provided in the required form, extent and structure to the Ministry of Health of the Slovak Republic (MH SR), the Statistical Office of the Slovak Republic, chief experts of MH SR as well as foreign data users, namely WHO, OECD and Eurostat.

The processed data are transformed into annual-, quarterly- and health status reports. NHIC publishes topical publications in the field of health statistics and activity of the Slovak Medical library.²¹ Further the outline of

²¹ Publications are sorted in four separate editions:

- Edition Health Statistics, available also in English on:
http://www.nczisk.sk/en/Publications/Edition_Health_Statistics/Pages/default.aspx
- Edition Health Statistics Yearbooks, available also in English on:
http://www.nczisk.sk/en/Publications/Edition_Health_Statistics_Yearbooks/Pages/default.aspx



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publications is listed in the Catalogue of Publications for the respective year. After processing the results of statistical findings, the publications are made available to users in both electronic and printed form and are also available for potential researchers.

NHIC can provide the researchers with available summarised and standardised information processed by NHIC. List of standardised statistical outcomes is available on the NHIC's website.²² Collected and processed data cannot enable direct identification of the patient (data subject), so cannot in any way contain personal data. Within such databases only standardised medical-administrative data in a standard collection of information are available.

Further the NCIH may provide the researchers (or other applicants) with un-standardised information processed from available information from their databases on the special request of researchers (or applicant in general). This is already a paid service.

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

- **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.

In general, in Slovakia the processing of health data is in principle prohibited. General exemption from this prohibition is laid down in Art 14 of Current Personal Data Protection Act and it is possible to do so if the data subject has given his/her explicit consent or if the processing of health data is performed for the purposes of providing healthcare and effecting public health insurance, provided that these data are processed by a provider of the healthcare, a health insurance company, a person exercising services related to providing healthcare or by a person exercising supervision of healthcare and on his behalf expertly skilled entitled person that is bounded by obligation to maintain secrecy over matters that are part of professional secret and obligation to maintain etiquette of the profession. Research involving the human person²³ and also the research studies or evaluation not involving the human person applies the research approval and a potential research participant must be informed before providing informed consent.

Such a database must be notified to the PDPO following the procedure set out in Art. 34 of the current Personal Data Protection Act. Slovak legislation does not contain any special provision in case the database is used for scientific research purposes.

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- Healthcare of the Slovak Republic in Figures, available also in English on: <http://www.nczisk.sk/en/Publications/Pages/Healthcare-of-the-Slovak-republic-in-figures.aspx>
 - Edition Analytical Publications, available also in English on: <http://www.nczisk.sk/en/Publications/Pages/Edition-Analytical-Publications.aspx>

²² Only in Slovak available on: http://www.nczisk.sk/Documents/infocentrum/stand_vystupy_2016.pdf

²³ In Art. 20 of the Healthcare Act defined as biomedical research.



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Special regime and the special registration of the database are laid down in Art. 37 of the current Personal Data Protection Act. This set out special registration under stricter requirements for the databases processing the health data, if their transfer to a third country not ensuring an adequate level of protection is expected.

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

- **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 databases are mentioned within the previous answers.

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.

b. Application of the national framework to the AEGLE cases

In the AEGLE project, the “research objective is to establish the use of Big data analysis in the prediction of outcomes in three working scenarios: Chronic Lymphocytic Leukaemia (CLL), Intensive Care Units and type 2 diabetes for the prediction of adverse outcomes. The research methodology is Big Data analysis to establish predictive values that may apply in three clinical scenarios and to see if this can be generalised to other healthcare disease models”.²⁴

To achieve its objective, the AEGLE project must base its approach on the study, and thus the processing, of data concerning health. This section aims to address each of the three proposed AEGLE cases, and to determine the requirements in general terms for access and the processes relevant to data under the Directive (the current framework) and the GDPR.

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.

The operations realised in the AEGLE project qualify as processing for research in the field of health purposes, and this is why Art. 6(5) of the current Personal Data Protection Act applies.

Once the data source has granted access to the database, before the start of any processing operation, a processing authorisation will have to be asked to PDPO through the application of Article 34 of the Act (or registration according to Art. 37 in case of databases processing health data and its if transfer to a third country not ensuring an

²⁴ AEGLE Grant Agreement, Annex 1, p. 83.

adequate level of protection is expected). Any further ethical or other type of approval is required. Also to elaborate appropriate safeguards and security documentation is necessary before authorisation (Art. 19 and 20).

If the data has been collected by health professionals during their activities, then they may transfer the data to researchers, and the data recipient will be bound by professional secrecy for this data.

The data subjects will have to not be informed of the further processing of the data as concerns them (due to Art. 6(5)).

Once the GDPR has been implemented:

In this case, the study requires pseudonymised or identifying data or sets of data. Once the PIA is realised, then PDPO's authorisation is necessary. 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. Moreover, the person concerned by the data can oppose the transfer. The data subject must be informed in conformity with the provisions set out in the GDPR.

2. Intensive Care Unit (ICU)

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

The operation realised in the AEGLE project qualifies as processing for research purposes in general because there is currently no special regulation and special provision in Slovakia dedicated for research in the field of health purposes.

The data is collected by health professionals in ICU services when they are treating patients. The processing of such data for research in the field of health assumes a compatible purpose. This processing finds its legal grounds in Article 6(5) of the Act. It is possible for health professionals to transfer the data they have collected to research, however, the recipient will be obliged to follow professional secrecy. Additionally, the data subjects will have to be informed about the transfer, and they may oppose it. The processing requires PDPO's authorisation (further processing). Before the start of any processing operation, a processing authorisation will have to be asked to PDPO through the application of Article 34 of the Act (or registration according to Art. 37 in case of databases processing health data and its if transfer to a third country not ensuring an adequate level of protection is expected). Any further ethical or other type of approval is required. Also to elaborate appropriate safeguards and security documentation is necessary before authorisation (Art. 19 and 20).

Once the GDPR has been implemented:

In this case, the compatibility between the purpose of the initial processing and the research project is presumed. In any case, the data subjects must be informed of the transfer of their data in conformity with the GDPR provisions.

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.

The operation realised in the AEGLE project qualifies as processing for research in the field of health purposes, and therefore Art. 6(5) current Personal Data Protection Act applies. Moreover, the purpose of AEGLE seeks to achieve is considered as compatible with the initial purpose, because the purpose is research in the field of health, and the processing will be completed in conformity with the principles set by the Act.

The further processing must be authorised by PDPO. The procedure is described in Article 34 of the Act. before the start of any processing operation, a processing authorisation will have to be asked to PDPO through the application of Article 34 of the Act (or registration according to Art. 37 in case of databases processing health data and its if transfer to a third country not ensuring an adequate level of protection is expected). Any further ethical or other type of approval is required. Also to elaborate appropriate safeguards and security documentation is necessary before authorisation (Art. 19 and 20).

Once the GDPR has been implemented:

Above mentioned provisions of GDPR are applicable.



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