'Big data analytics' and processing of health data for scientific research purposes : The finish legal framework

Research Protocol by Peter Hänninen, BORENIUS ATTORNEYS LTD
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1. Overview of the legal framework

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

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

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- 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?

Finland does not currently have a separate law on the processing of health data for research purposes.

The Personal Data Act (523/1999) governs the collection and the processing of personal data. It replaced the Personal Data File Act and was adopted in june 1999 in order to implement 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 basic rights and freedom of individuals are strongly emphasised in the Act.

The Personal Data Act is to be repealed with Data Protection Act, which is expected to be adopted by May 2018.

Processing of healthcare data in particular is currently governed by the Act on Electronic Prescriptions (2.2.2007/61)[1] and the Act on the Electronic Processing of Client Data in Social and Health Care Services (9.2.2007/159)[2], both adopted in 2007.

The Act on Electronic Prescriptions provides that introduction of electronic prescriptions is mandatory for pharmacies, healthcare units, and self-employed persons with practices in healthcare units' premises. For e.g. doctors and dentist who practise as self-employed persons outside healthcare units' premises, the electronic prescriptions are optional. The Act governs the rights and freedoms of individuals including, inter alia, provisions about patients' right of access to data, consent and right to object to transfer of data as regards electronic registers.

[1] https://www.finlex.fi/fi/laki/ajantasa/2007/20070061 (Finnish only)

[2] https://www.finlex.fi/fi/laki/ajantasa/2007/20070159 (Finnish only)

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Under the Act on the Electronic Processing of Client Data in Social and Health Care Services, public healthcare organisations are obliged to enter patient records in a nationally centralised archive. Deployment of the centralised archive is mandatory for private healthcare organisations, if they have an electronic system for long-term storage of patient records.

b. Revision of the current legal framework under the GDPR

How are the necessary changes to the national data protection framework, introduced by the GDPR, addressed in your country? What is the adopted legislative approach? Is the GDPR implemented in your country by an entirely new legislative text or via amendments to the current data protection law? Please explain.

In order to ensure Finland's compliance with the GDPR, a Government Bill for the Data Protection Act (HE 9/2018 vp)[3] has been introduced. With the supposed adoption of the Data Protection Act in May 2018 the Personal Data Act, along with the Act on the Data Protection Board and the Data Protection Ombudsman (389/1994)[4], will be repealed. The proposed Act would complement and clarify some of the provisions left for the member states' discretion.

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

Being a complementing and clarifying Act, the Data Protection Act follows the general principles set out in the GDPR. As opposed to the implementation of Directive 95/46, the national leeway of the GDPR does not enable enacting a comprehensive Act, but rather a complementing and clarifying Act, with most of the material content arising from the GDPR. Therefore, the Data Protection Act is supposed to be interpreted in parallel with the GDPR.

The Government Bill includes the areas where Member States are required to enact local legislation, such as provisions regarding processing of personal data for purposes of journalism or artistic or literary expression as well as provisions regarding penalties, such as criminal sanctions supplementing the administrative fines. Furthermore, the national leeway has been utilised in some fields where Member states may have local legislation. In the context of scientific research, relevant derogations to the data subjects' rights have been introduced which would be applied where necessary for the fulfilment of research purposes. Furthermore, the age limit for consent in relation to the offering of information society services has been proposed to be 13 years. Under the Data Protection Act the Data Protection Ombudsman would remain as the single Data Protection Supervisory authority in Finland, as discussed in detail below in Chapter 1.4.3.

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

The structure and legislative approach as a complementing and clarifying act is logical, and the utilisation of national leeway essentially to preserve the current sufficient guarantees for a functioning scientific operational environment is welcome. The vast amount of data in the Finnish patient registers and other health care data files is a terrific asset for quality research, and the efficient utilisation requires flexible enough legal framework. The legislative changes proposed are in line with longstanding Finnish policy to establish a competitive research environment and

[3] https://www.eduskunta.fi/FI/vaski/HallituksenEsitys/Sivut/HE_9+2018.aspx (Finnish only)

[4] https://www.finlex.fi/fi/laki/ajantasa/1994/19940389 (Finnish only)

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infrastructure which can efficiently utilize the, even in a global context, particularly extensive and well-structured national health records and archives.

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?

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

Under the current legal framework, there are two separate authorities: the Data Protection Ombudsman and the Data Protection Board, both of which are governed by the provisions of the Personal Data Act and by the Act on the Data Protection Board and the Data Protection Ombudsman (389/1994).

The Data Protection Ombudsman provides direction and guidance on the processing of personal data and supervises the processing, in order to achieve the Personal Data Act's objectives. The Data Protection Board, on the other hand, deals with questions of principle relating to the processing of personal data, where these are significant to the application of the Personal Data Act. One of the Board's main functions is to grant exceptions from the prohibition of processing sensitive data, as enabled in Article 8 Section 4 of Directive 95/46.

With the GDPR coming into force, and the Data Controllers themselves having to assess whether the processing is legal on the grounds provided in Article 6 and Article 9 of the GDPR, the key function of the Board as a permit authority is left redundant. Therefore, after the adoption of the Data Protection Act, there will only be one Data Protection Authority, the Data Protection Ombudsman. The Ombudsman's Office will carry on its duties with minor organisational changes, such as appointing one or more Deputy Ombudsmen and establishing an Expert Committee.

Act on the Data Protection Board and the Data Protection Ombudsman (389/1994) will be repealed with the Data Protection Act, and the Data Protection Ombudsman will be governed by Chapter 3 of the Data Protection Act. Although Data Protection Ombudsman will be working in connection with the Ministry of Justice, it will be an independent and autonomous governmental authority.

2. Transposition of Article 8.4 of Directive 95/46

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

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

Under the current data protection regime, health data is a special category of personal data and as such, its processing is prohibited by Section 11 Sub-section 1 Paragraph 4 of the Personal Data Act. However, under the Personal Data Act, the permitted grounds for processing of personal health data is firstly the data subject's explicit, adequately specified, voluntary and informed consent. Additionally health data may be processed, where there is a legal obligation to do so, such as with governmental bodies' obligation to maintain and process health data. Other derogations from the general prohibition for processing special categories of data are provided in Section 12 Sub-section 1 paragraph 6 of the Personal Data Act, under which it is permitted to process data for purposes of historical, scientific or statistical research. The rights of the Data Subject are set forth in Sections 24-29 of the Personal Data Act.

Under Section 14 of the Personal Data Act, personal data may be processed for purposes of scientific research, if: (1) the research cannot be carried out without data identifying the person and the consent of the data subjects cannot be obtained owing to the quantity of the data, their age or another comparable reason; (2) the use of the personal data file is based on an appropriate research plan and a person or a group of persons responsible for the research have been designated; (3) the personal data file is used and data are disclosed therefrom only for purposes of historical or scientific research and the procedure followed is also otherwise such that the data pertaining to a given individual are not disclosed to outsiders; and (4) after the personal data are no longer required for the research or for the verification of the results achieved, the personal data file is destroyed or transferred into an archive, or the data in it are altered so that the data subjects can no longer be identified.

Under the Act on the Openness of Government Activities (621/1999)[5], an authority may, on a case-by-case basis, grant permission to gain access to a secret document for purposes of scientific research, statistical compilations or the preparation of official plans or studies, if it is obvious that access will not violate the interests protected by the secrecy provision. When a decision of access is made, due consideration shall be given to the safety of the freedom of scientific research. If the information in the document has been handed over to the authority on the consent of the person whose interests are protected by the secrecy provision, the permission may be granted only subject to the conditions for use and access laid down in the consent.

Additionally, under Section 12 Sub-section 11 an insurer is permitted to process data collected in the course of its insurance activity and relating to the state of health, illness or handicap of the policyholder/claimant or the treatment or other measures directed at the policyholder/claimant, or data on the criminal act, punishment or other sanction of the policyholder/claimant or the person causing the damage, where necessary for the determination of the liability of the insurer.

[5] https://www.finlex.fi/en/laki/kaannokset/1999/en19990621.pdf (Unofficial English translation. Amendments to 907/2015 included)

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

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

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

Under Section 12 Sub-section 1 paragraph 10 of the Personal Data Act, a health care unit or a health care professional is allowed to process data collected in the course of their operations and relating to the state of health, illness or handicap of the data subject or the treatment or other measures directed at the data subject, or other data which are indispensable in the treatment of the data subject. The Personal Data Act allows for the processing of data for purposes of historical, scientific or statistical research purposes.

Under Section 12 Sub-section 2 Sensitive data shall be erased from the data file immediately when there no longer is a reason for its processing. The reason and the need for processing shall be re-evaluated at five-year intervals at the longest, unless otherwise provided in an Act or stated in a permission of the Data Protection Board.

Additionally, there are several exceptions to the rights of the data subjects as regards scientific research. Generally, under Section 26 of the Personal Data Act, data subjects have the right of access to the data in a personal data file as well as information of the regular sources, the uses and destinations of disclosed data. Under Section 27, however, there is no right of access, if the data in the file are used solely for historical or scientific research or statistical purposes.

b. The regime applying to the processing of personal data for health research purposes

Is there a specific regime applying to data processing for research in the field of health purposes? What is the scope? Which are the steps, and who are the key actors?

From which generally applicable data protection provisions are researchers exempted and under what conditions? For what reasons? From which provisions? What are the consequences?

There is no general legislative act governing solely the use of health data for research purposes, but rather the relevant legislative material can be found dispersed in a number of acts and decrees.

Currently, in addition to the Finnish Constitution and the Personal Data Act, there are multiple other laws governing the processing of personal data for health research purposes, most notably the Act and Decree on National Personal Data Registers Kept under the Health Care System, (556/1980)[6] and (774/1989) respectively, Act on the Electronic

[6] https://www.finlex.fi/fi/laki/ajantasa/1989/19890556 (Finnish only)

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Processing of Client Data in Social and Health Care Services (9.2.2007/159), Act on the Openness of Government Activities (621/1999) and Act on the Status and Rights of Patients[7]

Under the Act on National Personal Data Registers Kept under the Health Care system, public entities medical facilities acting as data controllers may grant access to the registers for purposes of scientific research, after having consulted the Data Protection Ombudsman.

The purpose of the Act on the Electronic Processing of Client Data in Social and Health Care Services is to promote data protection and data security as well as the compatibility and functionality of electronic processing of data in social and health care services by defining appropriate requirements and organising supervision. In essence, the Act requires the sensitive and confidential personal data to only be processed in an environment, where appropriate technical safeguards are implemented and that the processing fulfils data security obligations.

Act on the Status and Rights of Patients governs the patients' rights when providing health care services, where no other acts or provisions apply. The Act includes the fundamental provision on entries to the health care data file and processing thereof. Under Section 13 the data in the data files is confidential and access to third parties may not in principle be granted without the patients' written consent. However, there are derogations to this prohibition, and the Act refers to provisions in the Act on the Openness of Government Activities, Act on National Personal Data Registers as well as the Personal Data Act. Furthermore, National Institute for Health and Welfare may, in individual cases, grant permission to obtain information that is needed for purposes of scientific research from patient documents of more than one municipality or joint municipal board providing health and medical care services, from patient documents of a unit providing health care services referred to in the Act on Private Health Care and from patient documents of self-employed health care professionals.

The objectives of the right of access and the duties of the authorities provided in the Act on the Openness of Government Activities are to promote openness and good practice on information management in government, and to provide private individuals and corporations with an opportunity to monitor the exercise of public authority and the use of public resources, to freely form an opinion, to influence the exercise of public authority, and to protect their rights and interests. Principally, all official documents are in the public domain, unless specifically otherwise provided. Health care data being sensitive data, hence not in the public domain, may still be granted access to.

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

Under the GDPR the processing of health data for research purposes is regulated by Article 9(2)(j), which authorises the processing of health data if this "processing is necessary for archiving purposes in the public interest, scientific or historical research purposes or statistical purposes in accordance with Article 89(1) based on Union or Member State law which shall be proportionate to the aim pursued, respect the essence of the right to data protection and provide for suitable and specific measures to safeguard the fundamental rights and the interests of the data subject" (Emphasis added), and is combined with Article 89(1) ("Processing for archiving purposes in the public interest, scientific or historical research purposes or statistical purposes, shall be subject to appropriate safeguards, in accordance with this Regulation, for the rights and freedoms of the data subject. Those safeguards shall ensure that technical and organisational measures are in place in particular in order to ensure respect for the principle of data

[7] https://www.finlex.fi/en/laki/kaannokset/1992/en19920785_20120690.pdf (Unofficial translation. Amendments to 690/2012 included.

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minimisation. Those measures may include pseudonymisation provided that those purposes can be fulfilled in that manner. Where those purposes can be fulfilled by further processing which does not permit or no longer permits the identification of data subjects, those purposes shall be fulfilled in that manner").

a. The impact of the GDPR on the rules applying to processing for research in the field of health

Please provide a summary of the main relevant characteristics of the new law/Bill (as far as it is relevant for processing health data for research purposes).How is (or will be) Article 9(2)(j) implemented in your country?

The necessary changes to Finnish legislation required under the GDPR will mainly be introduced by the new Data Protection Act. The Data Protection Act is expected to be adopted by parliament by early May. Following the introduction of the Data Protection Act, subsequent changes will also be made to a range of sector specific legislation, including laws and regulations governing processing of health related data. Finland is also in the midst of a complete overhaul of the healthcare system and these changes, if introduced, will affect regulation related to data processing in this sector. There are also government initiatives ongoing for the amendment of the Biobank Act as well as to introduce a specific law governing the secondary use of healthcare data.

Under Article 89 Section 2 of the GDPR, the Member State may provide for derogations from the rights of the data subjects, including the right of access, right to rectification, right to restriction of processing and right to object. The act would include such derogations, where they are necessary for the fulfilment of research purposes, and where conditions and safeguards provided in the Article 89 Section 1 of the GDPR are in place. This approach is similar to the current legal framework. Under Section 31 of the Data Protection Act, derogations from the rights of the data subjects provided in Articles 15, 16, 18 and 21 would be subject to specific conditions: The processing is based on an appropriate research plan, there is a person or a group in charge of the research and that the data are processed and transferred only for purposes of scientific or historical research. Appropriate care should be of the confidentiality of the personal data processed. When the activities include processing of special categories of data, e.g. health data, the research is subject to carrying out a data protection impact assessment (DPIA) provided in Article 35 of the GDPR. A DPIA report would have to be delivered to the Supervisory Authority 30 days before the beginning of the processing activities.

The proposed Data Protection Act does not further detail the rules of processing health data for research or statistical purposes. As of April 2018, there are multiple Government bills introduced to amend the provisions under which processing of health data is possible following the application of the GDPR. The Government Bill for the Act on Secondary use of Social and Health Data is one of the main legislative elements as regards the research and statistical use of health data.

Provisions on processing healthcare data for e.g. statistical, research and educational purposes would be compiled in the Act on Secondary use of Social and Health Data (as described in further detail below).

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

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Act on Secondary use of Social and Health data would introduce a new, centralised Licensing Authority for social and welfare data application permissions as well as a service for permit applications. The Under Section 4 of the Act, the Licensing authority would operate in connection with the National Institute for Health and Welfare. Under Section 55 of the Act, the Licensing Authority would be responsible for monitoring the level of data protection and data security as regards the permit as well as whether the terms and conditions are complied with. In addition to the centralized licensing authority, personal health data would naturally also be available for research purposes under the provisions described above and contained in general legislation, such as the proposed Data Protection Act and the Act on the Openness of Government Activities (621/1999).

The Ministry of Social Affairs and Health has appointed a temporary steering group with a mission to direct and support the commencing of the operations of the Licensing Authority tasked with granting access to secondary uses of healthcare data. At the same time, the temporary steering group aims to develop the cooperation between the data controllers and secure the relevant stakeholders' participation in the service development.

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

The Licensing Authority would, to the extent necessary for the purpose, be responsible for combining from different sources the data and transfer them to the applicant without having to issue a license, where data requested is anonymous and aggregate level data. Such course of operation would also diminish administrative burden as well as hasten such data transfers, since currently the data requests are processed by each administrative controller individually and disclosure is based on various legal grounds, leading into long handling times.

The Finnish Innovation Fund ("Sitra") is preparing a one-stop-shop operator that would collect and coordinate healthcare data, with the working title Isaacus – The Digital Health HUB.[8] The project is co-operating extensively with the public and private sector, and the service should be available for researchers towards the end of 2018. Isaacus will operate under the responsibility of the Licensing Authority. The service will provide information on the available data as well as guidance. Research permits will be applied within the service, and permits granted to parties fulfilling the criteria.

Is it a logical change?

Having a centralised authority and operator will certainly simplify researchers' to access a wide array of health care data. Having the possibility to apply for access to essentially all of the relevant data files in one service will provide for unparalleled research possibilities, rather than having to apply for access from each data file separately. The diminishing administrative burden, as pointed out in the previous chapter, will release resources for more functioning access permit system.

is the supervisory authority involved? If yes, how?

The Supervisory Authority, along with other relevant authorities, is responsible for organising, directing and supervising operations performed in accordance with the Act under Section 55 of the Act on Secondary use of Social and Health data, as well as supervising compliance thereto. When the Licensing Authority is issuing permits for processing of data, it may consult the Data Processing Authority, but is under no absolute obligation to do so, under Section 44 of the Act. When commencing a new health data collecting operation or broadening the scope of existing

[8] https://www.sitra.fi/en/projects/isaacus-pre-production-projects/

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operations, however, the Licensing Authority would be required to consult the Supervisory Authority under Section 5 d of the Act on Amending the Act on the National Institute for Health and Welfare.

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

Under the Act on Secondary Use, the rights and freedoms of the data subjects would be required to be appropriately taken into consideration. The transfer of health data would only be permissible without authorities' permission when properly anonymised. The transfer of non-anonymised data would require a permit and compliance with the permit's terms and conditions. Additionally, under the Government Bill, non-anonymised data would generally have to be pseudonymised and processed in authenticated secure operating environment, where the use can be properly monitored. The access rights within the environment would have to be properly defined and restricted so as to protect the privacy of the data subject under the Section 22 Sub-section 1 of the Act.

When transferring pseudonymised data on grounds of multiple data utilisation plans, the data would need to be pseudonymised with an individual token for each plan, in order to avoid the processor being able to combine data to identify individuals, thus protecting the rights and freedoms of the data subjects.

4. Health data sources for research purposes

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

a. Sources of data and their regulation

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

- Direct collection from the patients:

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

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

Collection from health professionals and health institutions:

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

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

When collecting data directly from the patient for research purposes, the primary processing ground is the patient's (or any other data subject's) consent. Consent is defined in the Personal Data Act as any voluntary, detailed and conscious expression of will, whereby the data subject approves the processing of his/her personal data.[9] Consent may be in a written form or given orally, but a general consent at e.g. arrival at a health care facility does not constitute a "detailed" expression of will, and therefore is not valid. In addition, the research institution or hospital in question may require an ethical review of the research project prior to commencing the data collection.

Data subjects' electronic consent should meet the requirements for advanced electronic signatures as set out in Article 26 of the Regulation (EU) No 910/2014 of the European Parliament and of the Council of 23 July 2014 on electronic identification and trust services for electronic transactions in the internal market and repealing Directive 1999/93/EC.

Recently new legislation has been introduced which obliges entities which store the Patient File in electronic form to integrate their data to a national repository for patient data called "Kanta". Under the Act on the Electronic Processing of Client Data in Social and Health Care Services, public healthcare organisations are obliged to enter patient records in a nationally centralised archive. For private healthcare organisations the Deployment of the centralised archive is mandatory, if they have an electronic system for long-term storage of patient records. The aim of the Act is to further the data security of patient information processing, patients' access to information, and provide healthcare services with better patient safety and efficiency.

Under current regime, the The Social Insurance Institution of Finland ("Kansaneläkelaitos" or "Kela") is responsible for maintaining a patient file repository for archiving and processing health data under the Act on the Electronic Processing.

However, information recorded in the Patient Data Repository cannot *currently* be disclosed for scientific purposes. In order to access the data, researchers must contact the producer of the information in question in healthcare services directly.

[9] Section 3 sub-section 7 Personal Data Act.

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Under the current legal framework, the legal grounds on which data may be received from different data files depends on whether the source is private or a public or governmental entity. The former case is governed by the Personal Data Act whereas the latter by the Act on the Openness of Government Activities, although the provisions on disclosure are not substantially different.

Where the data source is a public or governmental entity, the right to disclose other than confidential personal data is provided in the Act on the Openness of Government Activities. When requesting access to a secret document, a personal data filing system controlled by an authority or any other document, access to which can be granted only subject to certain conditions, the person requesting access shall, unless specifically otherwise provided, declare the use to which the information is to be put, as well as give the other details necessary for determining whether the conditions have been met. Additionally, where necessary, the person requesting shall explain what arrangements have been made for the protection of the information.

Under section 14 of the Act on the Openness of Government Activities, the decision in general shall be made by the authority in possession of the document. However, a municipal council may, in municipal regulations provide a municipal body serving as an authority as referred to in the Act the right to transfer to a subordinate official the public authority to decide on the access. Access to the data shall be granted by an official or an authorised employee. The matter shall be considered without delay, and access to a document in public domain shall be granted in a month, whereas more complicated requests and requests concerning secret or confidential data shall be decided and access to the data granted within one month or the receipt of the request.

An authority may, on a case-to-case basis grant permission to gain access to a secret document for purposes of e.g. scientific research, if it is obvious that access will not violate the interests protected by the secrecy provision. When such a decision is made, due consideration must be given to the safety of the freedom of scientific research. If the information has been handed over to the authority based on consent, the permission may only be granted subject to the conditions for use and access laid down in the consent. The permission to access secret information may be granted for a fixed period and may be withdrawn where necessary.[10]

As regards health data possessed by National Institute for Health and Welfare, the access is granted by the Institute, after having consulted the Data Protection Ombudsman.

When requesting data from a private source, the controller disclosing the data is responsible for the legality of the data transfer under the Personal Data Act. Generally, the controller must receive a description of the purpose of the disclosure as well as other relevant information from the researcher requesting the data in order to assess the legality of the data transfer. The controller must also ensure, that the Section 14 of the Personal Data act is complied with. The controller must in general give a written statement of the transfer decision, especially if it is a negative one. In any case, the controller should duly document the decision, so that the legality of such decision may be assessed afterwards. Confidential information may generally not be disclosed without the data subjects' consent or unless specifically otherwise provided.

A researcher or a group of researchers planning to use health data in their research, must draw up a description of the personal data file, under Section 10 of the Personal Data Act. The description must include at least the

[10] Section 28 of the Act on the Openness of Government Activities.

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information on the data controller, the purpose of processing, a description of the data processed and possible transfers to third countries as well as a description of the principles in accordance to which the data file has been secured. This description must, in principle, be kept available to anyone.

Under current data protection regime, the data controller must notify Data Protection Ombudsman, where automated data processing is being planned, where such processing includes processing of sensitive data, the data are gathered on a register basis and such research file is not explicitly permitted by law. Under Section 36, the controller shall send the aforementioned description of personal data file along with a notification of launching of an automated decision making system.

Under the revised legislation, the centralized authorisation and access process is further detailed in Chapter 3.2.

- **PRIVATE DATABASES**

Under the current legal framework: please explain the rules currently applying for the setting up of and the use of a private database with health data for research purposes.

Setting up a private database with health data is not prohibited, but the processing of sensitive personal data for research purposes is subject to the provisions of the Personal Data Act. The grounds for processing are discussed above in Chapter 2.

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 Act on Secondary use of Social and Health Data, the Licensing authority would grant the licences and process the data requests regarding the secondary use of health and social data. The first step for researchers aiming to use health data would be to consult the advice services and the data resource descriptions to identify the data resources relevant for their purposes. An electronic service for requests would manage the requests for licence to access data, where the applicant would need to express the purpose for processing the data. The Licensing Authority would receive the applications directly from the electronic service.

When the licence is granted, the Licensing Authority would combine and edit the relevant data from different registers and transfer the data to a secure environment, to which the licensee would have a remote access for data processing.

- **PUBLIC DATABASES**

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

As discussed in Chapter 4.1 above, public authorities may disclose health data to a researcher or a group of researchers.

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

As discussed in Chapter 3.2 above, a central Licensing Authority is to be set up, which would in part be responsible for issuing, governing and supervising requests concerning health care data.

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

1. Type 2 Diabetes

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

The operations in the AEGLE project qualify as processing for research in the field of health purposes, which is permitted under Section 12 Sub-section 1 paragraph 6 of the Personal Data Act.

A researcher or a group of researchers planning to use health data in their research, must draw up a description of the personal data file, under Section 10 of the Personal Data Act, as described above in Chapter a.

2. Intensive Care Unit (ICU)

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

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

A researcher or a group of researchers planning to use health data in their research, must draw up a description of the personal data file under Section 10 of the Personal Data Act, as described above in Chapter 4.1.

Currently, an ethical approval is required by law for medical research, but not for processing of health care data for research purposes. However, a data controller may require obtaining such approval, and the need of requirement should be determined before requesting access.

-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 legislation, the authorisation and access process is further detailed in Chap-ter 3.2.

3. Chronic Lymphocytic Leukaemia (CLL)

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

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

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Under the current Biobank Act, a biobank may grant access to, study or otherwise process the samples and information stored by it provided that the intended use corresponds to the research area defined for the biobank and the criteria and conditions established for the processing of the sample, terms and restrictions provided in this act or elsewhere in law and determined by the biobank are observed in the research and in the processing of samples and information, the individual granted access to the samples or information holds the appropriate professional and academic qualifications for processing the samples and information, and the granting of access to the sample or information is in connection with the duties of the recipient.

The samples and information associated with them shall be coded prior to granting access to them for research purposes, unless there is specific reason for not doing so.

The codes used in connection with the granting of access are formed on a project-by-project basis as access is granted. The codes used in the storing of samples and information may not be given out by the biobank. Access to personal data may only be granted based on consent from the registered individual or some other person qualified to provide consent in the event that no other criteria is provided in this act for granting access to the information.[11]

A researcher or a group of researchers planning to use health data in their research, must draw up a description of the personal data file under Section 10 of the Personal Data Act, as described above in Chapter 4.1.

Currently, an ethical permit is not required for the processing of biobank data for research purposes, but a description of the ethicality of the research is required. Notwithstanding, the research institution or hospital in which the research is performed may nevertheless require an ethical approval before commencing the research work.

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

Under Section 21 of the Draft Government Bill for Biobank Act[12], a biobank could grant access to biobank data on fairly similar grounds to the current Act, the key difference being references to the compliance with the GDPR and other new relevant legislation, e.g. the Act on the Secondary Use of Social and Health Data.

Under Section 22 a Biobank could grant a temporary access to biobank data in individual cases. The request must be in a written form, and a data utilisation plan would have to be attached.[13] Furthermore, under Section 24, an access to biobank data could be granted for purposes of combining personal from data files in scientific research, where the conditions of the aforementioned Section 22 are met. When granted access, the data may be stored and processed for the time period set in the data utilisation plan or, where the temporary access permit issued by the Biobank further allows, the permitted time.

Where the access is sought to a private biobank, the Licence Authority would be responsible for granting licence as described above in chapter 3.2.

[11] https://www.finlex.fi/fi/laki/kaannokset/2012/en20120688.pdf

[12] https://www.lausuntopalvelu.fi/FI/Proposal/DownloadProposalAttachment?attachmentId=8582 (Finnish, downloads a .pdf-document.)

[13] Section 3 sub-section 17 of the Government Bill for the Act on the Secondary Use of Social and Health Data Section 3 sub-section 17: a data utilisation plan means a research plan that includes the purpose of the use of the data requested, the data controller and processors, the legal grounds for processing, and the relevant data protection and data security related essential issues, covering the entire lifespan of the data, including the storage and disposal or archiving of the data.

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