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

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Contents

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I. Overview of the legal framework

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

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

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

There are several laws and provisions concerned with processing of health data:

- Lov nr. 428 af 31. maj 2000 om behandling af personoplysninger (persondataloven)[1] : Act no. 428 of 31 May 2000 on processing of personal data[2]

The Act governs the collection and processing of personal data, and it also covers collection and processing of tissue samples which can be related to an identifiable person. The act was adopted in year 2000 to implement Directive 95/46/EC on the protection of individuals with regard to the processing of personal data and on the free movement of such data.[3] The Act has been amended several times; e.g. to implement the EU framework decision on the protection of personal data processed in the framework of police and judicial cooperation in criminal matters[4] and subsequently Directive 2016/680/EU.[5] It will undergo further changes with the implementation of the GDPR. As the Act both covers personal data and tissue samples, this report will include both data sources in its analyses.

- Lovbekendtgørelse nr. 191 af 28. Februar 2018 om sundhed (Sundhedsloven).[6] Consolidated Act no. 191 of 28 February 2018 on Health (Health Act)

[1] https://www.retsinformation.dk/Forms/R0710.aspx?id=828

[2] https://www.datatilsynet.dk/english/the-act-on-processing-of-personal-data/read-the-act-on-processing-of-personal-data/compiled-version-of-the-act-on-processing-of-personal-data/

[3] 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.

[4] Council Framework Decision 2008/977/JHA of 27 November 2008 on the protection of personal data processed in the framework of police and judicial cooperation in criminal matters.

[5] Directive (EU) 2016/680 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data by competent authorities for the purposes of the prevention, investigation, detection or prosecution of criminal offences or the execution of criminal penalties, and on the free movement of such data, and repealing Council Framework Decision 2008/977/JHA.

[6] https://www.retsinformation.dk/forms/R0710.aspx?id=199871

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The Health Act provides a legal framework for the provision of health care services (health promotion, health prevention and treatment) at national, regional and local level, and for the rights of patients and obligations of the health care services, e.g. in regards to informed consent to treatment and other interventions (e.g. abortion and organ donation). The Health Act also includes a number of provisions of particular importance for data processing. Patients' right to privacy is recognized, and access to and disclosure of health data within the health care services for the provision of care and other related purposes (e.g. quality assurance and administrative and planning purposes) is comprehensively regulated. Disclosure of health data for other purposes, such as scientific and statistical purposes and administrative purposes related to e.g. social security issues, is also regulated in the Health Act. The Health Act also contains provisions which requires health care professionals and institutions to report data to regional or national databases

- Lovbekendtgørelse nr. 1083 af 15. September 2017 om videnskabsetisk behandling af sundhedsvidenskabelige forskningsprojekter (Komiteloven).[7] Consolidated Act no. 1083 of 15 September 2017 on Research Ethics Review of Health Research Projects.[8]

The Act on Research Ethics Review of Health Research Projects governs the establishment of research ethics committees at regional and national level and lay down rules for ethical evaluation and authorization of health research projects. This also includes regulation of informed consent to collection and storage of data and tissue samples for scientific purposes (Articles 3-6)[9], and the further use of previously collected tissues samples for scientific purposes (Article 10).

- Lovbekendtgørelse nr. 1201 af 28. September 2016 (Bekendtgørelse af Arkivloven). Consolidated Act no. 1201 of 28 September 2016 on Archives (Archives Act)

The Archives Act lay down rules regarding archival activities of public authorities (both at national regional and local level) including obligations to keep records and for the transfer of records to the National Archive or another public archive. According to Article 21 of the Act, all records holding personal data covered by the Act on Processing of Personal Data must be transferred to a public archive, if they are to be kept after the normal time of erasure. This also applies to patient records as well as to health data kept in databases. The Act also authorises the Minister of Culture to lay rules regarding obligations to transfer data to public archives, and the obligation to transfer health data is specified in an executive order[10], which in details regulate the selection of patient records, special records kept by nurses, registries and data bases holding health data, which must be transferred for storage at a public archive. The Archives Act also includes provisions regarding storage of archival material hold by private actors in public archives.

The Archives Act governs access to the personal data kept in archives and lay down time limits for such access dependent on the character of the data. Records holding personal data about individuals' private (including economic) affairs are normally not accessible until after 75 years. However, it is possible to have access at an earlier

[7] https://www.retsinformation.dk/forms/R0710.aspx?id=192671

[8] http://www.nvk.dk/english/act-on-research (this version does not include revisions made after 2013).

[9] The informed consent requirements are further detailed in Executive Order no. 1264 of 2 December 2016 on informed consent to participation in a health research project and notification and supervision of health research projects (https://www.retsinformation.dk/Forms/R0710.aspx?id=185233), see especially Article 6.

[10] Executive order no. 266 of 25 March 2015 on storage and erasure of the Region's archival material (https://www.retsinformation.dk/Forms/R0710.aspx?id=169045)

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stage based on an assessment of a legitimate interest. This allows researchers to have access to archival material. The Danish National Archive has a special project on health data and assist researchers to get access to relevant material in the archive.[11] The Act on Processing of personal data establishes in Article 14 that data can be archived under the rules laid down in this Act.

- Lovbekendtgørelse nr. 977 af 9. August 2017 af Straffeloven.[12] Cosolidated Act no. 977 of 9 August 2017 of the Criminal Code)

The Criminal Code governs criminal responsibility and the associated penalties. According to Article 263-264, interferences in individual's private life, e.g. access to their private premises, letters, e-mails, and private matters, is a criminal offence, and Article 264d makes it punishable to disclose private pictures and information. Public employees and a number of other persons (including health care professionals) are, according to Article 152-152d, subject to professional secrecy and a duty of confidentiality. Sanctions for non-compliance with these rules are either a fine or imprisonment up to 6 months.

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

There is still no universal national EHR-system in Denmark. The EHR-system is built of various blocks operating at both local, regional and national level. Historically, the General Practitioners were the frontrunners in using EHRs and also in developing a common standard for EHRs. In the hospital sector the use of EHRs is also widespread. However, despite many years' attempts, it has not been possible to create a uniform national standard for EHRs within the hospital sector which relies on various regional solutions. However, all the five regions have now achieved to have one single EHR-system operating within each region. Consequently, most basic information in various parts of the health care sector has been digitalised, but a number of different EHR-systems are still operating. This makes it difficult to establish a national system for shared electronic health records.

However, some progress has been made, to ensure options for health care professionals (and patients) to access health records and registries at a national health platform – sundhed.dk – which is a digital platform set up by the Ministry of Health in collaboration with Danish Regions and Local Government Denmark (association of the 98 municipalities).[13] At this platform it is possible to have access to three national health record systems: The E-record (E-journalen)), the Shared Medication Record (Det Fælles Medicinkort), and the Lab Record (laboratoriesvar). The E-record is a centralised database, collecting information from hospitals in all the five Danish regions (E-record), and from GP's and other private practising health care professionals. Access to the records are governed by Article 42a-42e of the Health Act, which lay down rather detailed rules regarding the entitlements of various health care professionals to have access to the records for the purpose of providing medical treatment and rules regarding patient consent or patient opt-out options in this regard. The Shared Medication Record store information about patient's prescribed medication. Article 157 of the Health Act outlines the persons (health care professionals and other persons) who are entitled to have access to the Shared Medication Record, and it is further detailed in an executive order. Access, is only allowed for the purpose of providing treatment and care, and to identify patients

[11] See information about this project here: https://www.sa.dk/en/services/dda-danish-data-archive/dda-health/ (last accessed April 2018).

[12] https://www.retsinformation.dk/forms/R0710.aspx?id=192080

[13] In English version of the platform is accessible here: https://www.sundhed.dk/borger/service/om-sundheddk/ehealth-in-denmark/. See the most recent strategy for digital health care here: http://healthcaredenmark.dk/media/1611539/The-Danish-Digitalisation-strategy-2018-2022.pdf

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who receive an inappropriate medical treatment. In contrast to access to the E-record, patients do not have any influence on access to this record. Both health care professionals and patients can access these records by using NemID (easy-ID – a national digital signature platform)

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 Danish compliance with the data protection package, the current Act on Processing of Personal Data has been replaced by a new Act – the Data Protection Act – which was adopted 23 May 2018[14].

The new Act is based on a Bill presented by the Danish government to the Parliament on an "Act on supplementary provisions to the Regulation on protection of natural persons in connections with processing of personal data and on free movement of such data and on repealing directive 95/46/EF (General Regulation on Data Protection)" In October 2017.[15]

The Bill was based on a more than 1000 pages report from a committee appointed by the Minister of Justice to assess how the GDPR will affect Danish legislation.[16] The report was published in May 2017. Subsequently, a draft Bill was subject to a hearing process, which provided a number of comments, some of which has been taken into consideration when drafting the final Bill. The Bill included extensive explanatory comments including references to the report, and it provides a rather comprehensive picture of the Government's intention to make as few changes as possible to the current regulatory framework, and thereby to ensure the widest possible space for national discretion.

As the GDPR is directly applicable in Danish law, the new Data Protection Act only includes provisions which supplement the GDPR in areas where Member States within the framework of the GDPR are allowed to issue more detailed provisions (e.g. GDPR Article 6(2) and Article 6(3)), and areas where it is left to member states to decide on specific issues (e.g. Article 8(1) and Article 49(5)). The new Act also includes provisions which based on Article 23 and Article 89(2) restrict or derogate from the rights of the data subject, and provisions in areas where Member States are expected to adopt national rules (e.g. Article 43(1) and Article 51(1)). In line with the established Danish approach to implementation of EU-law, the provisions of the Act follow the wording of the GDPR closely.

[14] Act no. 502 of 23 May 2018 on supplementary provisions to the Regulation on protection of natural persons in connections with processing of personal data and on free movement of such data and on repealing directive 95/46/EF (General Regulation on Data Protection).

[15] Bill no. 68 of 25 October 2017. A link to the bill is available here: http://www.ft.dk/ripdf/samling/20171/lovforslag/l68/20171_l68_som_fremsat.pdf

[16] Ministry of Justice, "Databeskyttelsesforordningen – og de retlige rammer for dansk lovgivning" (The GDPR – and the Danish legal framework), Betænkning 1565,Vol. I-II. The report can be accessed and downloaded from here: http://jm.schultzboghandel.dk/upload/microsites/jm/ebooks/bet1565/del_I_bind1/index.html

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In parallel with the Parliamentary reading of the Bill for the Data Protection Act, another bill, regarding changes in a vast number of other laws as a consequence of the GDPR, was debated in the Danish Parliament.[17] This relates among others to the Health Act and the Act on Research Ethics Review of Health Research Projects.

This report relies on the Data Protection Act, the Bill, the committee's preparatory report, the explanatory comments to the Bill and on opinions articulated to the draft Bill.

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?

According to Article 10 of the current Act of Processing of Personal Data, personal data can be processed for scientific purposes provided the data are exclusively processed for scientific purposes and that the research project is of substantial public interest, and the data are necessary for carrying out the research project. If data processed for scientific purposes are to be transferred to third parties to be used for scientific purposes, the Data Protection Agency must approve the use/transfer (Article 10(3)). These criteria are considered to be the "suitable safeguards" required according to Article 8(4) of Directive 46/95/EF

The role of the Data Protection Agency in this domain differs, dependent on the sector, in which the research project is carried out, and the processing which will take place. Processing of sensitive information for scientific purposes carried out by researchers in *public* institutions (e.g. universities and university hospitals) must according to Article 45(1)(3) of the Act on Processing of Personal Data be notified to the Data Protection Agency, and the Agency has to give an opinion before the processing of data for scientific purposes can commence. In 2015, the Data Protection Agency made an organisational change of the notification system, so that it is not the individual researcher/research group, but the public authority, where the research takes place (e.g. the university, or the Regional Council (for hospital research)), which must make a so-called "umbrella notification" covering all current and upcoming research projects. This means that the Data Protection Agencies role in regards to research projects carried out in the public sector is rather limited, apart from approving the umbrella notifications. In regards to research projects carried out in the *private* sector (e.g. industry-based research or research projects carried out by patient organisations or NGO's) processing of data for research purposes must be notified to the Data Protection Agency, and the authorisation from the agency must be in place before the processing of data for research purposes can be initiated (Article 50 of the Act). The Data Protection Agency can also prescribe that certain conditions applies; e.g. in regards to data security and pseudonymisation.[18] However, some private sector research projects are exempted from the notification

[17] Bill no. 69 of 25 October 2017. A link to the bill is available here: http://www.ft.dk/samling/20171/lovforslag/L69/som_fremsat.htm. The Bill was adopted 23 May 2018 (Act no. 503 of 23 May 2018).

[18] The Agency requires that data, when transferred to third parties, are (as far as possible) pseudonymised, cf. Ministry of Justice, "Databeskyttelsesforordningen – og de retlige rammer for dansk lovgivning" (The GDPR – and the Danish legal framework), Betænkning 1565,Vol. I, p. 105. Guidelines (in Danish) are also available at the Agency's website. See here: https://www.datatilsynet.dk/offentlig/forskning/forskning-og-statistik-i-stat-og-kommuner/sikkerhedskrav-i-forbindelse-med-offentlig-forskning-og-statistik/

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requirement.[19] Research projects with an approval from a research ethics committee do not need to notify the Data Protection Agency, and the same goes for clinical trials of medicinal products or medical devices on human beings.[20] In addition, research projects carried out by students with the consent of the research participant, are not subject to notification. As will be clear, the Data Protection Agency's role in regards to private sector research projects, is also quite limited, as a vast part of health research projects carried out in the private sector are exempted from notification.

Irrespective of a notification requirement, the researchers must comply the with provisions in the Act on Processing of Personal Data. The Data Protection Agency has adopted a set of standard criteria as guidance for private sector research projects and also special criteria for research carried out in the pharmaceutical industry, which the data controller must comply with.[21]

Data collected for a scientific purpose based on Article 10 of the Act, cannot be used for other purposes (Article 10(2)). If a researcher would like to transfer data to a third party (e.g. a collaborating partner) for a research purpose, the Data Protection Agency must give its approval before the transfer takes place and may set up criteria for the further use of the data (Article 10(3)). As this is one of the safeguards required by the Directive, this is an important role for the Agency. Finally, the Data Protection Agency has the authority to conduct inspections of research projects.

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

In general, the role and competences of the Danish Data Protection Agency is very similar to the role under the current legislation. However, there are some changes in the Agency's competences in regards to processing for scientific purposes. With the GDPR and the new Data Protection Act, data controllers are normally not obliged to notify processing of personal data and required to have an authorisation to process data for a research purpose by the Agency. As – in practise – the role of the Danish Data Protection Agency in this regard has been limited the last years, this is not a major change. According to Article 10(3) of the new Data Protection Act, the obligation to obtain an approval for the transfer of personal data collected for research purposes to a third party, will not apply to all transfers but only to transfer of data to a third party outside the territorial scope of the GDPR[22], transfer of biobank material and in situations where data are transferred in connection with publication of research results in a well esteemed scientific journal. This is a modification of the previous competence of the Agency in this area.

In addition to the changes specifically relevant for processing of personal data for scientific purposes, the Data Protection Act introduces some minor revisions of the role and competence of the Data Protection Agency. This is to accommodate to the GDPR Chapter VI and other provisions relevant for the competences and duties of the Independent Supervisory Authority. Some specific tasks are clarified in the Act e.g. the consultancy role of the

[19] Article 49(3) and Article 50(3) of the Act on Processing of Personal Data and Executive Order no. 534 of 15 June 2000 on exemptions from the duty to notify certain kinds of processing of personal data initiated by a private data controller (with later amendments) https://www.retsinformation.dk/Forms/R0710.aspx?id=848

[20] Executive Order no. 410 of 9 May 2012 on changes of executive order on exemption from the duty to notify certain kinds of processing of personal data initiated by a private data controller https://www.retsinformation.dk/Forms/R0710.aspx?id=141758

[21] https://www.datatilsynet.dk/erhverv/forskere-og-medicinalfirmaer/standardvilkaar-for-forskningsprojekter/

[22] As defined in GDPR Article 3.

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Agency in the legislative process especially in regards to administratively issued rules and regulations (Article 28). The authority to perform audits and investigation sin regards to private sector controllers is also enhanced (Article 29(2)). The Data Protection Act also includes provisions regarding the relations and cooperation between the Agency and other European data protection authorities (Article 32-33). Finally, the Act expands the measures and sanctions the Agency can take and impose to correct and punish the breach of the controller's obligation as set out by the GDPR or the Act (Article 39-43).

II. Transposition of Article 8.4 of Directive 95/46

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

Article 8(4) of Directive 95/46/EF: "4. 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."

Remark, that the description of the Danish legislation in Section II refers to the law before GDPR came into force.

a. Transposition of Article 8.4 of Directive 95/46

In Denmark, data concerning health is a special category of personal data and as such its processing is prohibited by Article 7(1) of the Act on Processing of Personal Data. However, processing is legal with the consent of the data subject (Article 7(2)(1)), and furthermore if the processing is done for medical purposes (Article 7(5)).[23]

The current Danish law takes advantage of Article 8(4) and the possibility to make exemptions. According to Article 10 of the Act on Processing of Personal Data, sensitive personal data can be processed for scientific and statistical purposes provided data are exclusively processed for such purposes, that the research project is of significant public interest, and the data are necessary for carrying out the research project. If data processed for scientific purposes are to be transferred to third parties to be used for scientific purposes, the Data Protection Agency must approve the transfer (Article 10(3)). The criteria stipulated in Article 10 are considered to be the "suitable safeguards" required according to Article 8(4) of Directive 46/95/EF

Consequently, processing of sensitive personal data for scientific purposes is governed by a specific regime in the Act on Processing of Personal Data, complemented by other regulatory regimes, which are described in further details below.

[23] These provisions mirror, Article 8 of Directive 95/46/EF.

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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?

Use of personal data and tissue samples for research purposes in Denmark, is governed by a cluster of legal regulation. Apart from the Act on Processing of Personal Data, the Health Act, and the Act on Research Ethics Review of Health Research Projects have an impact. Whereas the Act on Processing of Personal Data applies to the processing of all kinds of personal data for any kind of research purpose, the two other acts are specifically targeting data processing in the field of health purposes. As will be clear below, the three legal areas are interwoven and partly overlapping.

The specific character of the research project determines the legal regime. It is necessary to distinguish between

- research which involves participation of the research participant, and
- research exclusively based on already collected data or tissue samples.

In the first category, the legal regulation depends on whether a physical/psychological intervention is involved, or whether the project only involves surveys or interviews. In the second category, it has importance whether tissue samples are involved. Bioinformatic data based on genomic analyses of a tissue sample, may also be covered by special regulation.

As various laws are involved and has an impact on processing of personal data, it is necessary to establish how the Act on the Processing of Personal Data relates to provisions in other laws regulating the processing of personal data. This is addressed in Article 2 of the Act on Processing of Personal Data, according to which the act does not apply if other laws give the data subject a higher level of data protection.

All health research projects involving human research subjects or human tissue in biobanks must according to Article 14(1) of the Act on Research Ethics Review of Health Research Projects obtain prior authorization from a research ethics committee (REC) before it can commence.[24] In contrast, research based exclusively on personal data from health records or databases does not need, and cannot obtain, REC authorization (Article 14(2)). The aim of the Act on Research Ethics Review of Health Research Projects is to ensure a balance between the interests and protection of research subjects and the interests of society and science. Its main focus, therefore, is on scientific quality, risk assessment and respect for research participants' autonomy and right to self-determination. It is stressed in Article 1 of the Act that in balancing the respective interests, the priority should be given to the

[24] If the research involves clinical trials of medicines or of medical devices, the special rules in Consolidated Act No. 99 of 16 January 2018 on Medicines also applies https://www.retsinformation.dk/forms/R0710.aspx?id=198319. An English version of the consolidated act (without the most recent amendments) is available here: https://laegemiddelstyrelsen.dk/en/about/targets-and-tasks/legislation/the-danish-medicines-act/~/media/0C65F89DCCB74F9AAA0C24D28BED3B59.ashx

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interests of the research participant. Data protection issues are not explicitly mentioned in the Act, but they are part of the risk assessment, and they are also addressed in an executive order issued with a legal basis in the Act.[25]

In situations, where a research project includes research participants who will, as part of their participation, have data collected (including data from health records) and maybe also tissue samples taken, the informed consent of the participant is mandatory. The REC will ensure that the participant receives proper information about the aim of the collection of data/tissue, the predicted future use and the storage period, and will also make an ethical assessment of the general framework for the sample collection. In this situation, the research participant has a stronger protection of the right to determine about the use of data for research purposes than what follows from the Act on Processing of Personal Data, and the informed consent requirement of the Act on Research Ethics Review of Health Research Projects has priority. Other issues related to the processing of the data collected as part of the research project are, however, governed by the provisions in the Act on Processing of Personal Data. The processing of personal data must be notified either to the Data Protection Agency or to the authority responsible for an umbrella notification, and the special provision in Article 10(2)-10(3) on processing of data for research purposes applies in regards to use and further use of data collected in a research setting.[26] If the research participant is a patient, and where research participation is part of the treatment, there may be additional requirement regarding e.g. information provided to the research participant based on the rules of informed consent stipulated in the Health Act.

Research based on identifiable tissue samples from a biobank are also subject to the requirement of prior authorisation from a REC. The normal rules of the Act on Research Ethics Review of Health Research Projects apply to biobank research projects, which imply that the tissue donor's informed consent is required. However, with regard to biobank research, Article 10 of the Act provides for derogation from this legal principle, and the REC may decide to make an exception, provided the project does not possess any risks or if it would be impossible or disproportionately difficult to obtain consent or proxy consent.[27] In situations where the REC decides to make an exemption from the informed consent requirement, the data subject/research participant is in a similar situation as stipulated in the Article 10 of the Act on processing of Personal Data, which can take place without the consent of the data subject. Accordingly, in this situation, a REC will make an assessment of the ethical aspects of the research projects, which will normally also include data protection concerns, before an authorization is granted. At the same time, the processing of data (tissue samples) taking place must be notified either to the Data Protection Agency or to the authority responsible for an umbrella notification, and the special provisions in Article 10(2)-10(3) on processing of data for research purposes applies in regards to use and further use of data collected in a research setting.[28]

Finally, research projects which are exclusively based on personal data stored in databases or patient records falls outside the scope of the Act on Research Ethics Review of Health Research Projects. Such projects must be notified either to the Data Protection Agency or to the authority responsible for an umbrella notification, and the special provisions in Article 10(2)-10(3) on processing of data for research purposes applies in regards to use and further

[25] Articles 6-8 of Executive order No. 1464 of 2 December 2016 on right to information and consent to participation in a health research project and on notification and control of health research projects.

[26] See more above in Section I.C.

[27] If the data subject has used the right to opt-out in regards to the further use of tissue samples according to Article 29 of the Health Act, the samples cannot be used for research purposes. See more below in Section II.C.

[28] See more above in Section I.C.

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use of data collected in a research setting applies.[29] For research based on data from patient records an approval from the Danish Patient Safety Authority is also necessary. According to Article 46 of the Health Act the Authority must approve disclosure of information in patient records for research purposes, if the research project has not obtained an authorisation from a REC. It is a condition that the project has significant societal interest, and the Patient Safety Authority can lay down further conditions for the processing of the data. It is furthermore a condition, that the data subject can only be contacted with the permission of the health care professional who has provided the treatment. Finally, the data may only be processed for scientific purposes, and any publication of the data must ensure that the data subject are not identifiable.

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

As explained in above in Section II.A the current Danish law takes advantage of Article 8(4) of Directive 46/95/EF and the possibility to make exemptions to the general rules on processing of sensitive data. According to Article 10 of the Act on Processing of Personal Data, sensitive personal data can be processed for scientific and statistical purposes provided the data are exclusively processed for such purposes, that the research project is of significant public interest, and the data are necessary for carrying out the research project. If data processed for scientific purposes are to be transferred to third parties to be used for scientific purposes, the Data Protection Agency must approve the use/transfer (Article 10.3).

In addition, there a few other exemptions. In regards to processing of personal data for research purposes in the private sector, research projects with an approval from a REC are exempted from the normal requirement to notify the Data Protection Agency, and the same goes for clinical trials of medicinal products or medical devices on human beings.[30] In addition, research projects carried out by students with the consent of the research participant, are not subject to notification. There are also exemptions in regards to some of the rights of the data subject. In regards to the data subjects right of access, there is an exemption in Article 32(4) of the Act of Processing of Personal Data, according to which the right of access does not apply when data are processed solely for scientific purposes and not kept longer than required for pursuing such purposes. The duty to notify the data subject about processing of data is no explicitly exempted in regards to processing of personal data for scientific purposes. However, according to Article 29(3) of the Act on Processing of Personal Data, exemptions are possible if it would be impossible or imply a disproportionate effort to fulfil this requirement. According to preparatory work to the Act, this is generally considered to be the case in regards to processing of data for scientific purposes.

[29] See more above in Section I.C.

[30] Executive Order no. 410 of 9 May 2012 on changes of executive order on exemption from the duty to notify certain kinds of processing of personal data initiated by a private data controller https://www.retsinformation.dk/Forms/R0710.aspx?id=141758

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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. As mentioned in Section II.A above, the current Danish law takes advantage of Article 8(4) and the possibility to make exemptions. According to Article 10 of the Act on Processing of Personal Data, sensitive personal data can be processed for scientific and statistical purposes under certain conditions which are perceived as suitable safeguards. First of all, it is a precondition that the research project is of significant public interest, and that the data are exclusively processed for scientific purposes. It is also required that processing of data necessary for carrying out the research project. The provision also regulated the further use of data collected for scientific purposes. First of all, further use is restricted to processing for scientific purposes. If data are to be transferred to third parties (both within Denmark, the EU and to third countries outside the EU) the Data Protection Agency must approve the use/transfer (Article 10(3)) and can prescribe criteria for further processing.

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?

Personal data concerning health which are collected in a clinical context are protected by *professional secrecy*.[31] However, as outlined above in Section II.B, this does not prevent the use of health data for research purposes. Dependent on the context, the researcher may have an obligation to observe professional secrecy, when the research project is carried out on patients who are receiving care as part of the research participation. In other situations, there is no professional secrecy applying to researchers as such. Researchers, who are public employees, are bound by professional secrecy due to their employment status, whereas this is not the case in the private sector. In case the researcher is not under an obligation to respect a special duty of professional secrecy, the general rules in the criminal code on protection of privacy, and the Act on Processing of Personal Data will protect the privacy of the research participant.

In some situations, it is mandatory to obtain an *express consent* from the data subject. This is the case when the data subject is taking part in a research project, and data or tissue samples are collected as part of the research project. The data collected can both be previously collected data stored in e.g. patient records or be directly collected for the research purpose. This is governed by the Act on Research Ethics Review of Health Research Projects (see more details above in Section II.B). In research projects based on tissue samples in biobanks, the RECs will often make an exemption from the requirement of obtaining an explicit consent. However, in this situation Article 29 of the Health Act, entitles patients to opt-out in regards to the further use of tissue samples for scientific purposes. To opt-out, patients must register in a special registry; the "Use of Tissue Registry". As outlined above in Section II.B, there is

[31] Article 30 of the Health Act.

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according to Article 10 of Act on Processing of Personal Data no consent requirement in situations, where a research project is based on data in health records and databases.

In regards to *diseased persons* the regulation depends on whether the research involves data or tissue samples. In situations, where a research project is based on exclusively on data from a diseased persons health record or information kept in databases, there is no consent requirement (Article 10 of Act on Processing of Personal Data). In case of tissue samples from a diseased person there is a rather complex regulatory situations, where the rules depend on, whether tissue samples are taken from the dead body or have been collected while the deceased person was still alive. In the first situation, it also has an impact whether tissue samples have been obtained as part of an autopsy or have been collected exclusively for a research project. If samples have been collected as part of an autopsy, the Health Act applies and according to Article 187, of the Act there must be a consent either from the diseased person (Article 187(1)), or an implicit/silent consent from the relatives (Article 187(2-3).[32] If the samples have been collected exclusively for a research purpose, the relatives must give an informed consent, in accordance with Article 8 of the Act on Research Ethics Review of Health Research Projects. In the second situations, where samples from diseased persons, which have been collected before the death and are kept in biobanks, will be used for a scientific purpose, the relatives can give informed consent in accordance with Article 8(2) of the Act on research Ethics Review of Health Research Projects. The REC may, however, decide to make an exemption from the consent requirement in accordance with Article 10 of the Act on Research Ethics Review of Health Research Projects (see more details above in Section II.B)

In regards to use of data from minors, or persons under guardianship it is again necessary to distinguish between situations, where the research participant is taking part in a research project, where data or tissue samples are collected as part of the research project, and situations where research is based on data or tissue stored in health records, databases or biobanks. According to Article 4-7 of the Act on Research Ethics Review of Health Research Projects it requires an explicit informed consent from the guardian, and in case of minors at the age of 15 years or older, also an explicit consent from the minor.[33] The same rules apply in regards to biobank research, unless the REC decides to make an exemption from the consent requirement based on Article 10 of the Act on Research Ethics Review of Health Research Projects. In this case, no consent is needed. Finally, if research is based on data in patient records and databases, there is no consent requirement (Article 10 of the Act on Research Ethics Review of Health Research Projects.

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

The data subject's right to information depends on the situation. In cases where the data subject is participating in a research project and an explicit informed consent is needed, there are certain requirements regarding the information, data subjects must have before they give consent. According to Articles 6-8 of Executive order No. 1464 of 2 December 2016 on right to information and consent to participation in a health research project and on notification and control of health research projects, data subjects must e.g. be informed about the rights of the responsible researcher (investigator) and sponsor (or representatives of sponsor) to obtain information from the

[32] See also Article 8(1) in the Act on Research Ethics Review of Health Research Projects.

[33] The REC can also decide, that a research participant who is 15 years or older, should have the authority herself/himself to make the decision, see Article 9 of the Act on Research Ethics Review of Health Research Projects.

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participants health records and from other sources for the monitoring of the project or for quality assurance. Research participants must also be informed about the legal rules governing the processing of their data. The REC will ensure that the participant receives proper information about the aim of the collection of data/tissue, the predicted future use and the storage period, and will also make an ethical assessment of the general framework for the sample collection.

In regards to the obligations to provide the data subjects with information as laid down in Article 11 of Directive 95/46/EF, there is no explicit exemptions covering processing of data for scientific purposes. However, according to Article 29(3) of the Act on Processing of Personal Data, exemptions are possible if it would be impossible or imply a disproportionate effort to fulfil this requirement. According to preparatory work to the Act, this is generally considered to be the case in regards to processing of data for scientific purposes.[34]

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?

Non-compliance with the Act on Processing of Personal Data may lead to sanctions. According to Article 69 data controllers may be liable to compensate damages. Criminal sanctions (fine or imprisonment up to 4 month) may, according to Article 70, also be imposed on data controllers for non-compliance with the rules and obligations outlined in the provision. There are no specific sanctions for non-compliance with the special provision (Article 10) regulating processing for scientific and statistical purposes. Non-compliance are subject to the same criminal sanctions as violations of other provisions.

As health research project may also be regulated by the Health Act and the Act on Research Ethics Review of Health Research projects, sanctions provided by these legal regimes may also be relevant. Non-compliance with some of the rules laid down in the Health Act, may lead disciplinary[35] or criminal sanctions[36].

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?

There are a few categories of research project, which can't profit from the special provision in Article 10 of the Act on processing of Personal Data, because the processing of personal data is not exclusively restricted to a research

[34] This mirrors Article 11(2) of Directive 95/46/EF.

[35] Consolidated Act No. 1028 of 28 August 2017 on the Rights to Complain and Receive Compensation within the Health Service.

[36] Health Act, Article 266 (fine or imprisonment up to 6 months for violation of Article 29), Article 271 (fine or imprisonment up to 4 months for violation of a number of provisions regulating access to and disclosure of health data)

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project but may have another purpose as well. Clinical trials and trials on medicinal products are subject to administrative and control requirements and procedures which involves access to health data obtained as part of the projects. As personal data are used for other purposes than research purposes it prevents such project from profiting from the easy access to health data provided by Article 10 of the Act on Processing of Personal Data. This implies that a specific consent from the data subject for the processing of data is necessary.

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

As seen above in Section II, possibilities for further use of personal data and tissue samples is important for scientific research for health purposes, and the regulatory framework is open towards this kind of research.

How is the notion of further processing regulated in your national framework? Are there specific conditions to the further processing for scientific research in the field of health purposes?

Both Article 10 of the Act of Processing of Personal Data and Article 46 of the Health Act provides for further use of data from health records, databases and other sources under certain conditions. In addition, Article 10 of the Act on Research Ethics Review of Health Research Projects allows for the further use of tissue samples stored in biobanks provided certain conditions are fulfilled.

In line with Article 6(1)(b) of Directive 95/46/EF, the purpose specification principle outlined in Article 5(2) of the Danish Act on Processing of Personal Data does not consider further processing of personal data for historical, scientific and statistical purposes for incompatible with the purpose, for which they were collected. This paves the way for further processing of health data collected in both a clinical and research context (and also in other contexts) for scientific purposes, and Article 10 of the Act profits from Article 8(4) of Directive 95/46/EF and allows for use of sensitive data for scientific and statistical purposes without the data subjects consent, provided certain conditions are fulfilled. As already outlined above in Section II.B, it is a precondition that the research project is of significant public interest, and that the data are exclusively processed for scientific purposes. It is also required that processing of data is necessary for carrying out the research project. The provision also regulates the further use of data collected for scientific purposes. First of all, further use is restricted to processing for scientific purposes. If data are to be transferred to third parties (both within Denmark, the EU and to third countries outside the EU) the Data Protection Agency must authorize the transfer (Article 10(3)) and can prescribe criteria for further processing.

The Health Act is specifically concerned with data collected in a clinical context. The Act presents a very complex framework for the governance of access to and disclosure of health data both with a clinical purpose and for other purposes, including for research purposes.[37] Together with the Act on Authorisation of Health Professionals,[38] the Health Act also contains a number of duties for health care professionals to report data to regional or national health databases, which are intended to be used for e.g. scientific purposes. Consequently, the Health Act is promoting and facilitating the further use of data collected in a clinical context for scientific purposes. According to

[37] See Articles 41-49.

[38] Consolidated Act No. 990 of 18 August 2017 on Authorisation of Health Professionals and on Provision of Health Care Services https://www.retsinformation.dk/Forms/R0710.aspx?id=192522

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Article 46(1) of the Health Act, further use of data from health records for scientific purposes is possible, provided the project has obtained an authorisation from a REC. If the project is not authorized by a REC, which will be the case for all projects which are exclusively based on personal data, the Danish Patient Safety, must authorize access to the data subject's health record (Article 46(2)). It is a condition that the project has significant societal interest, and the Patient Safety Authority can lay down further conditions for the processing of the data. It is furthermore a condition, that the data subject can only be contacted with the permission of the health care professional who has provided the treatment (Article 46(3)). Finally, the data may only be processed for scientific purposes, and any publication of the data must ensure that the data subject are not identifiable (Article 48).

Finally, the Act on Research Ethics Review of Health Research Projects is also open to further use of tissue samples collected in relation to a previous research project or in a clinical and other context. Article 10 of the Act facilitates the further use of tissue samples by allowing for exemptions from the normal informed consent requirement, if the project does not possess any risks, or if it would be impossible or disproportionately difficult to obtain consent or proxy consent. The researcher must also investigate if some of the data subjects has made use of the right laid down in Article 29 of the Health Act to opt-out for further use of tissue samples by registering in the "Use of Tissue Register". The Act on Research Ethics Review of Health Research Projects does not apply to research projects exclusively based on health data. However, the Act allows the REC to prescribe conditions for an authorisation of a research project, and in projects involving comprehensive genetic analyses (as e.g. Next Generation Sequencing) it is a standard requirement, that the bioinformatics data obtained through a comprehensive genetic analyses of a tissue samples obtained from a biobank, must not be used for other research activities without a new authorisation from the REC.[39] This is due to the fact, that the bioinformatics data are reflecting the "pool" of sensitive information stored in the tissue sample, and that research performed on the data generated from these samples must be protected at the same level as the samples - even though that formally speaking these kinds of data does not fall within the jurisdiction of the Act.

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

According to Article 29 of the Danish Act on Processing of Personal Data, the data controller has a duty to notify the data subjects when data are collected from other sources than the subject herself. The controller must inform the data subject about whom the data is collected from (the identity), the purpose of the processing, the categories of data and recipients, and the rules of the rights of access and the rights to rectify (Article 29(1)). However, according to Article 29(3) of the Act, data subjects shall not be notified if they already have the information, or if the disclosure of the data is expressly laid down in by law or regulations. In some situations, data subjects are informed about the further use. E.g. if data are collected in relation with participation in a research project, it may follow from the information provided to the research participants that data may be shared with other research groups at a later stage (with the permission of the Data Protection Agency and in some situations also the authorization from a REC). Is also possible to make other exemptions from the duty to notify, if notification proves impossible or would involve a disproportionate effort. According to the preparatory work this is expected to be the case in regards to a number of research projects.

Moreover, under Article 35, a data subject may object to the further use of data concerning him/her by the controller. If this right is justified, the controller must not process the data further. However, according to the

[39] See guidelines issued by the National Committee on Health Research Ethics (available here: http://www.nvk.dk/~/media/NVK/Dokumenter/Guidelines-on-Genomics-Research.pdf?la=da).

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preparatory work it is presumed that objections should not be taken into consideration in regards to processing of data for scientific purposes.

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

As already mentioned above, the exemption to the duty to notify stipulated in Article 29 of the Act on Processing of Personal Data, may apply in cases of further use of data for other purposes, as it may turn out to be impossible or disproportionate difficult to inform data subjects whose data are used for research project involving data from a vast number of data subject.

If the data subject is not notified, it may be difficult to object to the further use of data. But in case a data subject finds out – or suspect – that data is used for research purposes, it is – in principle – possible to object to the processing. However, as mentioned above it is presumed that such objections should not be taken into consideration in regards to processing of data for scientific purposes. In regards to tissue samples there is also a right to – on beforehand – opting-out in regards to the further use of samples for research purposes (Article 29 of the Health Act).

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

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

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

The overall aim of the Danish Government in regards to the GDPR is to ensure that the current legal framework will – as far as possible – be applicable in the future as well. Consequently, the aim is to profit from the room provided for national discretion. There are, however, some areas where changes are either necessary due to the GDPR or is considered relevant seen from a Danish perspective.

As outlined above in Section 1.B, the Danish government presented a Bill to the Parliament on an "Act on supplementary provisions to the Regulation on protection of natural persons in connections with processing of personal data and on free movement of such data and on repealing directive 95/46/EF (General Regulation on Data Protection)" In October 2017.[40] The Bill was adopted 23 May 2018. As the GDPR is directly applicable in Danish law, the new Data Protection Act only includes provisions which supplement the GDPR in areas where Member States within the framework of the GDPR are allowed to issue more detailed provisions (e.g. GDPR Article 6(2) and Article 6(3)), and areas where it is left to member states to decide on specific issues (e.g. Article 8(1) and Article 49(5)). The

[40] Bill no. 68 of 25 October 2017. A link to the bill is available here: http://www.ft.dk/ripdf/samling/20171/lovforslag/l68/20171_l68_som_fremsat.pdf

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Act also includes provisions which based on GDPR Article 23 and Article 89(2) restrict or derogate from the rights of the data subject, and provisions in areas where Member States are expected to adopt national rules (e.g. Article 43(1) and Article 51(1). In line with the established Danish approach to implementation of EU-law, the provisions of the Data Protection Act follow the wording of the GDPR closely.

There are a number of provisions in the Act which are relevant for processing of health data for research purposes. The Act specifically deals with health data in Article 7(3), (with reference to GDPR Article 9(2)(h)) and in Article 10 (with reference to GDPR Article 9(2)(j) and Article 89(1)) which is concerned with processing of data for scientific and statistical purposes. As mentioned above, it is the Governments clear intention to ensure that the previous possibilities for processing of data for scientific and statistical purposes provided by Article 10 in the Act of Processing of Personal Data can be sustained. Consequently, Article 10 of the Data Protection Act aims to ensure that it will still be possible to process sensitive data without the explicit consent of the data subject. However, some changes to the previous regulation has been enacted; either to accommodate to the GDPR or to address other concerns or interests. In contrast to the previous situation, the Data Protection Act does not require the authorisation of the Data Protection Agency in all situations where sensitive data, based on Article 10, will be transferred to third parties. In the future, such authorisation is, according to Article 10(3)(1) of the Act, only necessary where the data are to be transferred to third parties outside the territorial scope of the GDPR[41], or in cases where tissues samples is transferred to third parties both within and outside the territorial scope of the GDPR (Article 10(3)(2) of the Act). In addition, authorisation is according to Article 10(3)(3) of the Act needed in situations where data will be transferred with a view to be published in a widely recognised scientific journal (or the like). In the preparatory work to the Data Protection Act it is explicitly mentioned that a few other Acts – including the Health Act and the Act on Research Ethics Review of Health Research Projects – will be affected by the changes in the regulation. A later analysis of the coherence of the regulation is announced with a view both ensure a high level of protection of personal data, and a clear and understandable regulatory framework for the users of data for scientific and statistical purposes.[42]

Apart from the special provision specifically targeting processing of sensitive data for scientific and statistical purposes, the Data Protection Act reflects a certain concern for the protection of genetic data collected for health-related purposes. The purpose specification principle is addressed in Article 5 of the Act, and according to Article 5(3), the responsible minister is entitled to – within the scope of Article 23 of GDPR – to issue an executive order to entitle public authorities to process data for purposes which are not compatible with the purposes for which they were collected. However, this option does not exist in regards to genetic data collected for health-related purposes, which may only be further processed for purposes compatible with the original purpose of collection.

Finally, Article 31 of the Data Protection Act could also be relevant for processing of data for research in the medical field. The provision refers to Article 49(5) of the GDPR and gives the Data Protection Agency the authority to prohibit, restrict or suspend transfer of sensitive data to third countries for reasons of public interests.

[41] See Article 3 of the GDPR.

[42] Preparatory comments to Bill no. 68 of 25 October 2017, Section 2.3.6.3.

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

Under the previous legal regime, a number of health research projects would have to be notified to the Data Protection Agency or to an authority to which competence to receive notifications had been delegated (umbrella notification). In line with the GDPR, the general obligations to notify and obtain prior authorisation is omitted, and according to the Data Protection Act, no special rules will apply in regards to prior authorisation of health research projects. Instead data controllers will have to keep records, and in some cases also to appoint a DPO and make a data protection impact assessment.

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

According to the preparatory work to the Data Protection Act, it has not been seen as necessary to adopt special rules regarding prior authorisations of processing of sensitive data for research purposes. The duty to maintain records of the processing activities laid down in Article 30 of the GDPR together with to obligation to appoint a DPO according to Article 37 of the GDPR, and to perform a data protection impact assessment is seen as a sufficient mechanism.[43] In addition, Article 10(4) of the Actl authorises the Data Protection Agency to issue binding guidelines regarding transfer of data. The obligation to perform a data protection impact assessment according to Article 35 of the GDPR is not mentioned in the preparatory work but would be relevant for a number of health research projects and could potentially show that prior consultation of the Data Protection Agency is necessary according to Article 36 of the GDPR.

As explained above in section IV.A, Article 10(3) of the Data Protection Act requires prior authorisation when data collected for a research purpose based on Article 10 of the Act are to be transferred to third parties outside the territorial scope of the GDPR[44], or in cases where tissues samples is transferred to third parties both within and outside the territorial scope of the GDPR (Article 10(3)(2) of the Act). In addition, authorisation is according to Article 10(3)(3) of the Act needed in situations where data will be transferred with a view to be published in a widely recognised scientific journal (or the like).

In regards to health research projects based on data from patient records, the obligation to have a prior authorisation from the Danish Patient Safety Authority will remain the same. As outlined above in Section II.B, the Patient Safety Authority must, according to Article 46 of the Health Act, approve disclosure of information in patient records for research purposes, if the research project has not obtained an authorisation from a REC.

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

Article 89(2) of the GDPR provides the opportunity of derogations to: the right to access (GDPR Article 15), the right to rectify (GDPR Article 16), the right to restrict the processing (GDPR Article 18) and the right to object (GDPR Article

[43] Preparatory comments to Bill no. 68 of 25 October 2017, Section 2.3.6.3.

[44] See Article 3 of the GDPR.

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21). However, these derogations are only available if those rights would seriously impair or make impossible the scientific purpose of the processing.

The Data Protection Act makes use of the possibility to derogate from some of the rights of the data subject, and according to Article 22(5) of the Act, the rights laid down in Article 15, Article 16, Article 18 and Article 21 do not apply in regards to processing of data which takes place exclusively for scientific or statistical purposes.

V. Further processing for research purposes under the GDPR

The notion of further processing under the GDPR:

Further processing is defined in the GDPR as "the processing of personal data for purposes other than those for which the personal data has been initially collected".[45] As a point of departure the purpose specification principle outlined in GDPR Article 5(b) reads that further processing is allowed, provided its purpose is compatible with the purpose for which the data has been initially collected. As outlined more detailed below, further processing for scientific and historical research, and statistical and archival purposes, is not considered to be incompatible with the purposes, or which data were collected.[46]

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.

If the legal basis for the processing of data is based on the data subject's consent (e.g. GDPR Article 6(1)(a) or GDPR Article 9(2)(a), the assessment of compatibility will rely on an interpretation of the scope of the consent. Where processing is based on legal basis in EU or Member State Law, the compatibility assessment relies on an interpretation of the legal basis.

Where the 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.[47] 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

[45] GDPR, recital 50.

[46] See also GDPR, Article 89(1).

[47] See also GDPR, recital 50.

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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.

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. As scientific research is often based on existing data collected in e.g. a clinical context or for previous research purposes, and as there is a vital public interest in promoting research to the benefit for society, the GDPR reflects the assumption, there is a common interest in scientific research.

While the GDPR adjusts the purpose specification principle in the context of further processing for research purposes, it also requires (Article 9(2)(j) and Article 89(1)) that appropriate safeguards must be in place to pay sufficient attention to the data subject's rights and freedoms. This is in line with Article 2 of the Council of Europe Convention on Human Rights and Biomedicine, which stresses the primacy of the human being.[48] As outlined in Article 89(1) appropriate safeguards includes technical and organisational measures, such as pseudonymisation or anonymisation.[49] However, other safeguards may also be applied based on national law and other relevant legislation e.g. regarding clinical trials.[50]

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

As outlined above in section IV.A, the GDPR is directly applicable in the Danish law, and the new Data Protection Act only includes provisions which supplement the GDPR in areas where Member States within the framework of the GDPR are allowed to issue more detailed provisions, and areas where it is left to member states to decide on specific issues. The Act also includes provisions which based on Article 23 and Article 89(2) restrict or derogate from the rights of the data subject, and provisions in areas where Member States are expected to adopt national rules.

In regards to processing of data for health research purposes, Article 10 of the Data Protection Act is of particular relevance. This provision aims at maintaining the previous legal framework regarding processing of personal data for scientific purposes. Consequently, Article 10 aims to ensure that it will still be possible to process sensitive data without the explicit consent of the data subject. However, the Data Protection Act includes some changes to the

[48] Council of Europe, Convention for the Protection of Human Rights and Dignity of the Human Being with regards to the Application of Biology and Medicine: The Convention on Human Rights and Biomedicine, Oviedo 4.IV.1997, European Treaty Series – No. 164. Article 2: The interests and welfare of the human being shall prevail over the sole interest of society.

[49] See also GDPR, recital 156.

[50] See GDPR, recital 156. See also Ministry of Justice, "Databeskyttelsesforordningen – og de retlige rammer for dansk lovgivning" (The GDPR – and the Danish legal framework), Betænkning 1565,Vol. II, p. Section 10.5.3.5.3

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previous regulation; either to accommodate to the GDPR or to address other concerns or interests. In contrast to the previous legal situation, the Data Protection Act does not require the authorisation of the Data Protection Agency in all situations where sensitive data, based on Article 10, will be transferred to thirds parties. With the new Ac, such authorisation is, according to Article 10(3)(1), only necessary where the data are to be transferred to third parties outside the territorial scope of the GDPR[51], or in cases where tissues samples are transferred to third parties both within and outside the territorial scope of the GDPR (Article 10(3)(2)). In addition, authorisation is according to Article 10(3)(3) of the Act needed in situations where data will be transferred with a view to be published in a widely recognised scientific journal (or the like). In the preparatory work it is explicitly mentioned that some other Acts – including the Health Act and the Act on Research Ethics Review of Health Research Projects – will be affected by the enactment of the Data Protection Act. A later analysis of the coherence of the regulation is announced with a view both ensure a high level of protection of personal data, and a clear and understandable regulatory framework for the users of data for scientific and statistical purposes.[52]

The Data Protection Act also introduces another novelty compared to the previous regulation. According to Article 10(2) of the Act, personal data collected for scientific purposes based on Article 10(1) may – as previously – not be used for other purposes. However, Article 10(5) of the Act gives the Minister of Health (after consultation with the Minister of Justice) authority to issue binding rules (executive orders) regarding exemptions from Article 10(2) in situation where vital interests of the data subject speak in favour of this. According to the preparatory work this exemption is introduced to ensure the vital interests of the data subject in situations where a health research project or statistical analyses reveals a specific risk of having a serious disorder (including genetic disorder) for which prevention or treatment is available. This could also include situations where data is processed as a support for making clinical decisions regarding provision of personalised/precision medicine. It is anticipated that rules, which will be issued based on Article 10(4), will include safeguards to ensure proper respect for the data subjects interests and rights.[53]

Apart from the special rules regarding further processing for scientific purposes, introduced by the Data Protection Act, there is a more general provision allowing public authority to process personal data for purposes, which are not compatible with the purposes for which they were collected, based on public interests. It is, however, clearly stated in the preparatory work, that this does not apply to processing of data based on Article 10 of the Act.[54] As mentioned above in section IV.A, the responsible minister is according to Article 5(3) of the Act, entitled to – within the scope of Article 23 of GDPR – to issue an executive order to entitle public authorities to process data for purposes which are not compatible with the purposes for which they were collected. However, this option does not exist in regards to genetic data collected for health-related purposes, which may only be further processed for purposes compatible with the original purpose of collection.

[51] See Article 3 of the GDPR.

[52] Preparatory comments to Bill no. 68 of 25 October 2017, Section 2.3.6.3.

[53] Preparatory work, specific comments to Article 10. The also Ministry of Justice, "Databeskyttelsesforordningen – og de retlige rammer for dansk lovgivning" (The GDPR – and the Danish legal framework), Betænkning 1565,Vol. II, p. 985, which refers to GDPR, recital 159, as a legal basis for introducing this regime.

[54] Preparatory comments to Bill no. 68 of 25 October 2017, comments to Article 5.

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VI. 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?

In the current legal framework, the definition of personal data implies that anonymous data are not covered by the Act on Processing of Personal Data. There is no general provision in the Act regarding pseudonymisation or anonymisation, but the Data Protection Agency may prescribe certain conditions to be fulfilled when authorising processing of personal data. In regards to processing of personal data for health research projects the Agency has some standard requirements which include recommendations regarding pseudonymisation of data.[55]

The Bill is referring to pseudonymisation as a safeguard to be considered in regards to e.g. processing of personal data for research purposes.

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.

Data concerning an individual's health is sensitive data according to Danish law. Tissue samples, which are related to an identifiable person, are also considered sensitive data. As explained above in Section II.B there are different laws which must be taken into consideration when collecting health data directly from individuals. If the collection involves an *intervention*, e.g. a blood test or some kind of measurement or monitoring, the project will have to comply with the rules laid down in the Act on Research Ethics Review of Health Research Projects. Among other things, this implies obtaining a specific, written consent from the person after having provided proper written and oral information. Furthermore, the researcher must apply for authorisation at a REC, and the research project can't commence, before the authorisation is granted. Apart from the Act on Research Ethics Review of Health Research Projects, the researcher must also comply the Act on Processing of Personal Data. This is also the case, if the collection of data from the individual does not involve an intervention. Normally, interviews and filling out surveys are not considered an intervention. According to Article 7(2)(1) of the Act on Processing of Personal Data, an explicit consent for processing of sensitive data for research purposes is required. The special rule in Article 10 of the Act regarding processing of data for research purposes, does not apply, when data are collected directly from the individual. In addition, the data subject's right to information according to Article 28 must be observed. This implies that the data subject must be informed about the identity of the controller, the purposes of the processing, and any further information which is considered necessary to enable the data subject to safeguard his interests (e.g. the categories of recipients and the rules on the right of access to and the right to rectify the data relating to the data

[55] The Agency requires that data when transferred to third parties are (as far as possible) pseudonymised. See Ministry of Justice, "Databeskyttelsesforordningen – og de retlige rammer for dansk lovgivning" (The GDPR – and the Danish legal framework), Betænkning 1565, Vol. I, p. 105. Guidelines from the Data Protection Agency are available here: https://www.datatilsynet.dk/offentlig/forskning/forskning-i-regionerne/

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subject). Finally, if the data subject is a patient, and the patient participate in the research project as part of the treatment, the provisions in the Health Act regarding obtaining informed consent and on access to and transfer of data (see above in Section II.B) must be observed.

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

The Data Protection Act does not substantially modify the conditions in regards to collection of data directly from the individual for research purposes.

- **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 data from health professionals and health institutions for research purposes follows the regulation for further use of health data, irrespective of whether the researcher is a health professional and would use data from his/her own patients in a research project, or a researcher with no connection to the health care facility. In this situation the research does not fall under the scope of the Act on Ethics Review of Health Research Projects, unless the research involves tissue samples from a biobank. As outlined above in II.B, processing of data in this situation is subject to Article 10 in the Act on Processing of Personal Data, which implies that data can be collected if the research project is of significant public interest, and that the data are exclusively processed for scientific purposes. It is also required that processing of data necessary for carrying out the research project. Article 10 also regulates the further use of data collected for scientific purposes. First of all, further use is restricted to processing for scientific purposes. If data are to be transferred to third parties (both within Denmark, the EU and to third countries outside the EU) the Data Protection Agency must authorize the use/transfer (Article 10(3)) and can prescribe criteria for further processing. In addition to the Act on Processing of Personal Data, the Health Act also regulates access to data in health records. As explained above in Section III, Article 46(1) of the Health Act, allows for further us of data from health records for scientific purposes, provided the project has obtained an authorisation from a REC. If the project is not authorized by a REC, which will be the case for all projects which are exclusively based on personal data, the Danish Authority of Patient Safety, must authorize access to the data subject's health records (Article 46(2) of the Health Act). It is a condition that the project has significant societal interest, and the Patient Safety Authority can lay down further conditions for the processing of the data. It is furthermore a condition, that the data subject can only be contacted with the permission of the health care professional who has provided the treatment (Article 46(3)). Finally, the data may only be processed for scientific purposes, and any publication of the data must ensure that the data subject are not identifiable (Article 48).

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

The Act does not substantially modify the conditions of access to data gathered by health professionals and health care establishments.

- **PRIVATE DATABASES**

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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 provide database must comply the Act on Processing of Personal Data. Consequently, there must be a legal basis in the Act to collect and store information in the database. The legal basis depends on the purpose of the database. If set up with a view to provide medical treatment or for the management of health care services, Article 7(5) of the Act allows for processing of sensitive data in this situation, provided the data controller is subject to an obligation of professional secrecy. It may also be necessary under the current regulation to notify and get a permission from the Data Protection Agency. If the database is set up specifically for a research purpose, it could rely on Article 10 of the Act for the collection and storage of data in the database, as long as data are not collected directly from the data subject, which would require an informed consent.

When setting up a private database it may also be necessary under the current regulation to notify and get an authorisation from the Data Protection Agency. Normally, authorisation from the Data Protection Agency is necessary for private actors processing sensitive data. However, according to Article 49 of the Act on Processing of Data, such authorisations is not needed if the processing is carried out by a licensed health care professional and provided the processing is necessary to perform his/her professional activities. But the processing must still be notified to the Data Protection Agency. If, however, sensitive data are processed by a private hospital, it is mandatory both to notify and get an authorisation from the Agency. However, as explained in more details in section I.C, some private sector research projects are exempted from the notification requirement.[56] Research projects with an approval from a research ethics committee do not need to notify the Data Protection Agency, and the same goes for clinical trials of medicinal products or medical devices on human beings.[57] In addition, research projects carried out by students with the consent of the research participant, are not subject to notification.

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

The new Data Protection Act does not effectively change the conditions applying to the setting up of a private data base. It will, however, not be required to notify and get a permission from the Data Protection Agency, apart from in special cases.

- **PUBLIC DATABASES**

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

There are numerous databases and biobanks in the field of health in Denmark. Some have been built for clinical purposes (clinical databanks/biobanks), for administrative (including planning) purposes, or with a view to ensure and enhance quality of care (quality assurance databases). A vast number of databases and biobanks are build up in relation to a research projects or are established with the purpose of being used for research (research databases/biobanks). The National Health Data Agency is hosting of large number of national data bases including

[56] Article 49(3) and Article 50(3) of the Act on Processing of Personal Data and Executive Order no. 534 of 15 June 2000 on exemptions from the duty to notify certain kinds of processing of personal data initiated by a private data controller (with later amendments) https://www.retsinformation.dk/Forms/R0710.aspx?id=848

[57] Executive Order no. 410 of 9 May 2012 on changes of executive order on exemption from the duty to notify certain kinds of processing of personal data initiated by a private data controller https://www.retsinformation.dk/Forms/R0710.aspx?id=141758

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e.g. the Danish National Patient Register, the Danish Birth Register, and the Diabetes and the Cancer Register.[58] For biobanks, the Danish National Biobank is an organizational umbrella for a number of the largest and most important Danish biobanks, such as the Patobiobank and the PKU Biobank.[59] The Danish National Biobank creates an infrastructure by means of a register that connects information from biobanks with information on individual disease codes and demographics from national administrative databases within Denmark. This should facilitate access for researchers who wish to obtain data from the databases and biobanks involved.

In general, the Danish society promotes and facilitates databases research. Access to the public databases and biobanks depends on the purpose of the access, who is hosting the database, and how the individual database has organised access for research purposes. When researchers wish to have access to identifiable information, they will in any case have to comply the Act on Processing of Personal Data, including the obligation to notify either the Data Protection Agency or to an authority to which competence to receive notifications has been delegated (umbrella notification). The data controller will also have to ensure that access is compliant with Article 10 of the Act on Processing of Personal Data, which includes an assessment of the societal importance of the research project, and of the necessity of getting access to personal data to carry out the project. If aggregated data are available and provided the research can rely on such data, they may be openly accessible.

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 new Data Protection Act, the rules applicable to the use of public databases do not effectively change. It will, however, not be required to notify and get a permission from the Data Protection Agency, apart from in special cases.

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 Lymphotic Leukemia (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". [60]

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.

[58] A link to a list the databases (only in Danish) which are available for research purposes can be found at this link https://sundhedsdatastyrelsen.dk/da/forskerservice/for-du-soger/registre-og-dokumentation

[59] The Danish National Biobank is located at the Statens Serum Institut, which is a public body coming under the Ministry of Health.

[60] AEGLE Grant Agreement, Annex 1, p. 83.

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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.

As the AEGLE project makes use of data obtained in a clinical context the main regulation under the current legal framework will be the Act on Processing of Personal Data and the Health Act. The Act on Research Ethics Review of Health Research Projects does not apply as, the research does not involve participation of human beings or tissue samples.

As in this case patients have provided a consent to the further use of data for research purposes, it must be assessed whether the consent is sufficiently explicit to allow for the use of data based on Article 7(2)(1) of the Act of Processing of Personal Data. In this case, the further use for research purposes is based on the data subject's consent. If the consent is not sufficiently explicit, Article 10 of the Act on Processing of Personal Data allows for the further processing of personal data collected in a clinical context for research purposes without the data subject's consent, provided the research is of significant societal interest, and access to the data are necessary to carry out the research. In this case, certain restrictions apply in regards to the further use of data and sharing of data with third parties.[61] In both situation, the processing may also be subject to notification/umbrella notification and authorisation (certain private sector research projects).

As data are collected in a clinical setting, an approval from the Danish Health Safety Authority will also be necessary according to Article 46 of the Health Act, if data from patients' records will be included.

According to the current regulation, data subjects have certain rights including the right to be informed about the processing, and the right to have access to data. According to a

Article 29 of the Danish Act on Processing of Personal Data, the data controller normally has a duty to notify the data subjects when data are collected from other sources than the subject herself. The controller must inform the data subject about whom the data is collected from (the identity), the purpose of the processing, the categories of data and recipients, and the rules of the rights of access and the rights to rectify (Article 29(1)). However, according to Article 29(3) of the Act, data subjects shall not be notified if they already have the information, or if the disclosure of the data is expressly laid down in by law or regulations. In some situations, data subjects are informed about the further use. E.g. if data are collected in relation to a research project, it may follow from the information provided to the research participants that data will be shared with other research groups at a later stage. It is also possible to make exemptions from the duty to notify, if notification proves impossible or would involve a disproportionate effort. According to the preparatory work this is expected to be the case in regards to a number of register-based research projects.

Once the GDPR has been implemented:

The new Data Protection Act will not change the legal framework significantly apart from the obligation to notify and obtain an authorisation from the Data Protection Agency, which will not be required apart from in special cases. Instead, there will be an obligation to keep records, and in some cases also to appoint a DPO and make a data

[61] See more in Section III.

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protection impact assessment. The conditions applying in cases, where the processing of data based on Article 10 of the Act on Processing of Personal Data, will be loosened, and sharing data with thirds parties covered by the scope of the GDPR will be possible without prior permission of the Data Protection Agency. In addition, it will also in special situation be possible to use the data obtained in the research project for providing treatment to the benefit of the patient.

In regards to the right to be notified about the processing of data the exemption provided in GDPR Article 14(5)(b) applies. Furthermore, the new Data Protection Act makes use of the possibility provided by Article 23(1) of the GDPR to derogate from some of the rights of the data subject, and according to Article 22(5) of the Act, the rights laid down in Article 15 (right to access), Article 16 (right to rectify), Article 18 (right to restrict the processing) and Article 21 (rights to object) do not apply in regards to processing of data which takes place exclusively for scientific or statistical purposes.

2. Intensive Care Unit (ICU)

In this case AEGLE uses data generated by ICU devices without collecting the patient's consent (after pseudonymisation). As in the first case, this project makes use of data obtained in a clinical context, and the main regulation will be the Act on Processing of Personal Data and the Act on Health. The Act on Research Ethics Review of Health Research Projects does not apply as, the research does not involve human beings or tissue samples.

As there is no explicit consent from the data subjects, the further processing of data can rely on Article 10 of the Act on Processing of Personal Data, which allows for the processing of personal data for research purposes without the data subject's consent. It is a precondition that the research is of significant societal interest, and that access to the data are necessary to carry out the research. In addition, certain restrictions apply in regards to the further use of data and sharing of data with third parties.[62] In both situation, the processing may also be subject to notification/umbrella notification and authorisation (certain private sector research projects).

As data are collected in a clinical setting an approval from the Danish Health Safety Authority will also be necessary, if data from patient records are used (Article 46 of the Health Act). If this is the case, it is a condition that the project has significant societal interest, and the Patient Safety Authority can lay down further conditions for the processing of the data. It is furthermore a condition, that the data subject can only be contacted with the permission of the health care professional who has provided the treatment. Finally, the data may only be processed for scientific purposes, and any publication of the data must ensure that the data subject are not identifiable.

As in the first case, the data subjects will not have to be informed of the further processing of the data and will not be entitled to have access to data.

Once the GDPR has been implemented:

[62] See more in Section III.

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The new Data Protection Act will not change legal framework apart from the obligation to notify and obtain an authorisation from the Data Protection Agency, which will not be required apart from in special cases. Instead, there will be an obligation to keep records, and in some cases also to appoint a DPO and make a data protection impact assessment. The conditions applying in cases, where the processing of data based on Article 10 of the Act on Processing of Personal Data, will be loosened, and sharing data with third parties covered by the scope of the GDPR will be possible without prior permission of the Data Protection Agency. In addition, it will also in special situation be possible to use the data obtained in the research project for providing treatment to the benefit of the patient.

In regards to the right to be notified about the processing of data the exemption provided in GDPR Article 14(5)(b) applies. Furthermore, the new Data Protection Act makes use of the possibility provided by Article 23(1) of the GDPR to derogate from some of the rights of the data subject, and according to Article 22(5) of the Act, the rights laid down in Article 15 (right to access), Article 16 (right to rectify), Article 18 (right to restrict the processing) and Article 21 (rights to object) do not apply in regards to processing of data which takes place exclusively for scientific or statistical purposes.

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.

It is not completely clear, whether the researchers will obtain samples from the biobank and subsequently analyse the samples to obtain data, or whether samples have already been analysed and the project will only make use of the data obtained through the analyses. In both cases the research will be in conformity with the purpose specification principle.

If the project collects samples from a biobank, an authorisation from a REC is necessary according to the Act on Research Ethics Review of Health Research Projects, and as a general rule the consent of the research subject must be obtained. In this case, there is general consent, but this is not valid in a research context. However, according to Article 10(5) of the Act on Research Ethics Review of Health Research Projects, an REC may decide to make an exception if the project does not possess any risks or if it would be impossible or disproportionately difficult to obtain consent or proxy consent. The data controller will, however, have to check whether the patient has made use of the right to opt-out granted in Article 29 of the Health Act.[63] If this is the case, the samples cannot be used.

If the project relies on data obtained through analyses of the samples, the situation will be equivalent to the two previous cases. The further processing of data is justified in Article 10 of the Act on Processing of Personal Data, which allows for the processing of personal data for research purposes without the data subject's consent. It is a precondition that the research is of significant societal interest, and that access to the data are necessary to carry out the research. In addition, certain restrictions apply in regards to the further use of data and sharing of data with third parties. In both situation, the processing may also be subject to notification/umbrella notification and authorisation (certain private sector research projects).

[63] See more details above in section II.C.

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As data are collected in a clinical setting an approval from the Danish Health Safety Authority will also be necessary, if data from patient records are used (Article 46 of the Health Act). If this is the case, it is a condition that the project has significant societal interest, and the Patient Safety Authority can lay down further conditions for the processing of the data. It is furthermore a condition, that the data subject can only be contacted with the permission of the health care professional who has provided the treatment. Finally, the data may only be processed for scientific purposes, and any publication of the data must ensure that the data subject are not identifiable.

As in the two other AEGLE case, the data subjects will not have to be informed of the further processing of the data and will not be entitled to have access to data.

Once the GDPR has been implemented:

If the project collects samples from a biobank with a view to analyse them, the legal situation is the same as under the current legal framework outlined above.

If the project makes use of data (based on previous analyses of the tissue samples), the legal situation is the same as in the two previous AEGLE cases. This means, that there will be very few changes compared to the current legal framework. There will be no obligation to notify and obtain an authorisation from the Data Protection Agency, apart from in special cases. Instead there will be an obligation to keep records, and in some cases also to appoint a DPO and make a data protection impact assessment. The conditions currently applying in cases, where the processing of data based on Article 10 of the Act on Processing of Personal Data, will be loosened, and sharing data with third parties covered by the scope of the GDPR will be possible without prior permission of the Data Protection Agency. In addition, it will also in special situation be possible to use the data obtained in the research project for providing treatment to the benefit of the patient.

In regards to the right to be notified about the processing of data the exemption provided in GDPR Article 14(5)(b) applies. Furthermore, the new Data Protection Act makes use of the possibility provided by Article 23(1) of the GDPR to derogate from some of the rights of the data subject, and according to Article 22(5) of the Act, the rights laid down in Articles 15 (right to access), Article 16 (right to rectify), Article 18 (right to restrict the processing) and Article 21 (rights to object) do not apply in regards to processing of data which takes place exclusively for scientific or statistical purposes.

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