

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

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Partners

1. Overview of the German 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.

In Germany, a number of laws need to be considered when it comes to the processing of health data for research purposes. On the one hand this is due to the established federal system. Germany consists of 16 federal states (Bundesländer or Länder) and the federation (Bund) and legislative competences in the field of processing personal data are split up. On the other hand there are general acts on the processing of personal data as well as special laws which may supersede these general norms depending on the individual circumstances. As will be seen below, a multitude of federal and Länder provisions implement the Data Protection Directive.

Federal Data Protection Act (FDPA), Data protection acts on the Länder level, special acts

According to the legislative powers as established by the [German constitution \(Grundgesetz - GG\)](#), the Data Protection Directive was implemented at the federal level and at the Länder level. At the federal level, the [Federal Data Protection Act - FDPA \(Bundesdatenschutzgesetz – BDSG\)](#) must be considered. Each Land also has a general data protection act. Next to these general acts, special data protection provisions in other acts may be of relevance depending on the individual circumstances. There are federal acts, such as the Genetic Diagnostics Act (Gendiagnostikgesetz - GenDG) or specific Länder acts, e.g. hospital acts (Krankenhausgesetze), health service acts (Gesundheitsdienstgesetze) or cancer registration laws (Landeskrebsregistergesetze).

The FDPA first entered into force on 1.1.1978. It was reformed with notification from 14.1.2003 and last amended by an amending act from 31.10.2017. With the [Act to Adapt Data Protection Law to Regulation \(EU\) 2016/679 and to Implement Directive \(EU\) 2016/680](#) (Gesetz zur Anpassung des Datenschutzrechts an die Verordnung (EU) 2016/679 und zur Umsetzung der Richtlinie (EU) 2016/680 (Datenschutz-Anpassungs- und -Umsetzungsgesetz EU–DSAnpUG-EU)), a new FDPA – BDSG neu (2018) was passed, which will enter into force on 25.5.2018. On the same date, the old FDPA will cease to be in force. The data protection acts of the Länder also undergo reform. Many of them are still pending.

The FDPA and the data protection acts on the Länder level govern the collection and processing of personal data. The FDPA applies to public bodies that are either part of or influenced by the federation and to the processing of personal data by private bodies in so far as they process or use data by means of data processing systems, or collect data for such systems (section 1 (2) BDSG). In case public bodies that are part of the Länder or are influenced by them process personal data for research, mostly the data protection acts of the Länder must be considered (e.g. section 2 (1) Data Protection Act of Lower Saxony ([Niedersächsisches Datenschutzgesetz – NDSG](#))). However, next to the general data protection acts, special laws may also provide data protection provisions that have to be taken into consideration. For example, hospitals in Hamburg will have to comply with the Hospital Act of Hamburg which

provides specific data protection regulations. In Lower Saxony, where the Hospital Act does not provide specific data protection provisions, the FDPA applies in case the hospital is privately owned; otherwise if the hospital is a public entity of the Land Lower Saxony the Data Protection Act of Lower Saxony is the relevant law. For the processing of personal data by church organisations, the Act on Church Data Protection ([Gesetz über den kirchlichen Datenschutz – KDG](#)) must be considered.

Hospital Acts

As mentioned above, a number of the Bundesländer have special data protection provisions in their hospital acts for patient data regulating the processing of patient data for treatment, but also for research purposes.¹ Such provisions supersede the general data protection acts.² The general data protection acts could, however, still be relevant if the hospital act does not constitute exhaustive provisions.

Cancer Register Acts

Each Bundesland also enacted cancer register acts. Cancer registers have several functions, amongst others they shall provide data from cancer patients for scientific research.³ The cancer register acts entail special provisions for the protection of the data of registered cancer patients and under what circumstances the data may be accessed for research purposes.

Health Service Acts

Communities of the Länder are charged with reporting about the health circumstances of their population, especially health risks, health condition and health behaviour by health service acts (Gesundheitsdienstgesetze). For these purposes, non-personal and anonymized information is collected and evaluated in terms of epidemiological aspects (municipal reports – kommunale Berichterstattung).⁴

Criminal Code

Next to the regime of data protection, the provision section 203 (1) of the [Strafgesetzbuch - StGB](#), which is the [German Criminal Code](#), sanctions breaches of medical confidentiality. According to this provision, i.a. a physician who unlawfully disclosed a secret of another which was made known to him or her in his or her capacity as a physician, shall be liable to imprisonment or a fine. When it comes to the physician-patient-relationship, any patient data falls in the secret category and must not be unlawfully disclosed.

¹ A good overview is presented in Schneider, U. K., Sekundärnutzung klinischer Daten - Rechtliche Rahmenbedingungen, 2015.

² Meier, A., Der rechtliche Schutz patientenbezogener Gesundheitsdaten, 2003, pp.17-18; Pöttgen N., Medizinische Forschung und Datenschutz, 2008, pp. 67-68: The Federation has the concurrent legislative powers to legislate on data protection in privately owned hospitals, but has not conclusively regulated data protection in that context. That is why the Länder could enact specific provisions on data protection also for privately owned hospitals.

³ E.g. section 1 (2) No 4 Act on the Epidemiological Cancer Register in Lower Saxony ([Gesetz über das epidemiologische Krebsregister Niedersachsen](#), <http://www.kk-n.de/rechtliches/>)

⁴ e.g. section 8 Health Service Act of Lower Saxony ([Niedersächsisches Gesetz über den öffentlichen Gesundheitsdienst – NGöGD](#)).

Professional Law

In each Land, physicians underly professional law – Berufsordnung, e.g. in Lower Saxony physicians must comply with the [Berufsordnung der Ärztekammer Niedersachsen](#). These laws entail similar provisions concerning medical secrecy obligations of the physician, e.g. section 9 Berufsordnung der Ärztekammer Niedersachsen. These provisions also provide an obligation for physicians who use personal data for their research to receive advice from an ethics committee before they pursue their research, e.g. section 15 (1) Berufsordnung der Ärztekammer Niedersachsen.

Medicinal Products Act

Aim of the [Medicinal Products Act \(Arzneimittelgesetz – AMG\)](#) is to guarantee the safety in respect of the trade in medicinal products, ensuring in particular the quality, efficacy and safety of medicinal products.⁵ The act also provides provisions for the protection of clinical trial subjects.⁶ A clinical trial in the sense of the act is any investigation on human subjects intended to investigate or verify the clinical or pharmacological effects of medicinal products, or to identify adverse reactions or to study the absorption, distribution, metabolism or excretion, with the aim of ascertaining the safety or efficacy of the medicinal product.⁷ The AMG entails specific provisions for the processing of personal data in the context of clinical trials and with regard to the involvement of an ethics committee and administrative authorisation

Genetic Diagnostics Act

When it comes to the processing of genetic data for research, the Genetic Diagnostics Act [Gendiagnostikgesetz - GenDG](#) may also have to be taken into account. Although the scope of application explicitly excludes the applicability of the act to genetic analysis and the management of data and specimen for research purposes⁸, it is argued that this exclusion clause is only relevant if the data have been collected and analysed only for research purposes. If the initial collection was also for treatment purposes the Genetic Diagnostics Act still applies with the consequence that further processing for research would be only possible if the concerned patient has given his or her informed consent for the usage of his or her data for research purposes.⁹ An exception is made if only anonymized findings without the genetic fingerprint are concerned as these do not differ from usual patient data.¹⁰

Social Acts - Sozialgesetzbücher

⁵ Section 1 Medicinal Products Act.

⁶ Sections 40-42b Medicinal Products Act.

⁷ Section 4 (23) Medicinal Products Act; Non-interventional trials are not covered. “A non-interventional trial is a study, in the context of which findings resulting from persons' treatment with medicinal products are analysed using epidemiological methods; the treatment, including the diagnosis and monitoring, shall not follow a predetermined trial protocol but shall result exclusively from current medical practice”. Pure compassionate trials (Heilversuche) are also not covered (Schneider, U. K., op. cit., p. 67).

⁸ Section 2 (2) No 1 Genetic Diagnostic Act.

⁹ Schneider, U. K., op. cit., p. 54-59.

¹⁰ Schneider, op. cit, p. 57-58.

The social acts ([Sozialgesetzbücher](#)) contain specific data protection provisions for the processing of health data for research, e.g. sections 287, 303e SGB V, section 206 SGB VII, section 75 SGB X or section 98 SGB XI.

This list gives an overview of the most important acts. It is, however, not exhaustive. There are other acts which may also come into play, e.g. the Transplantation Act ([Transplantationsgesetz – TPG](#)) or the Medical Device Act ([Medizinproduktegesetz – MPG](#)), which also provide special data protection provisions.

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

Do shared electronic patient records exist in your country? How is the sharing of electronic patient records regulated? Can data stored in these records be used for research purposes?

In Germany, two forms of electronic health records dealing with the sharing of health data can be found: electronic patient record (elektronische Patientenakte) and electronic health record (elektronische Gesundheitsakte).

When receiving medical treatment, an electronic health insurance card is mandatory for all medically insured persons. According to section 291a (3) sentence 1 lit. 4 Social Act No 5 ([Sozialgesetzbuch Fünftes Buch - Gesetzliche Krankenversicherung – SGB V](#)), this card must allow for the collection, processing and use of data concerning results, diagnoses, therapies, medical reports and vaccinations, so that these measures can be documented across institutions and cases (called elektronische Patientenakte). This means that all medically insured persons have an insurance card capable of being used as shared electronic health (or patient) record (carrier). Nevertheless, such processing of data requires explicit consent of the data subject, which needs to be documented on the insurance card, and can be withdrawn at any time (section 291a (3) sentence 4, 5 SGB V).

Access to the shared electronic health record data is restricted to the collection, processing and use which is necessary for medical care and treatment, and only persons enlisted in the provision are allowed to do so, which are: doctors, dentists, pharmacists, medical professionals, pharmacy technicians and personnel, and (partly) psychotherapists - as well as the insured persons themselves (see section 291 (4) Social Act No 5). According to section 291a (8) sentence 1, second half-sentence Social Act No 5, it is not allowed to agree upon the use of the data stored on the insurance card for purposes other than those mentioned in section 291 (4). This cannot be superseded by an explicit consent of the insured person, because section 291a (8) sentence 1, second half-sentence Social Act No 5 is of conclusive nature not allowing recourse to the more general data protection rules, like the principle of consent.¹¹ Therefore, access to data stored on this insurance card aiming at using them for research purposes is not allowed, not even if the insured person consented to such a use.¹²

Additionally, there is the “personal” electronic health record (persönliche elektronische Gesundheitsakte). Other than the electronic patient record, it is a record administered by the patients themselves, in most cases using an

¹¹ Domain specific data protection rules are conclusively regulated by Social Act 5, not allowing recourse to the more general data protection rules, see Federal Social Court of Germany (Bundessozialgericht), Judgment of 10.12.2008 - B 6 KA 37/07 R, BSGE 102, 134 (Abs. 36-37), accessible online via <https://openjur.de/u/170356.html>.

¹² See Schneider, U. K., Sekundärnutzung klinischer Daten - Rechtliche Rahmenbedingungen, 2018, p. 380. And storing of additional research data (different from data already stored for medical care and treatment) if consented to by the insured person is not allowed either, see Schneider, U. K., p. 384.

online service provided by a (private) third party¹³. It can be used to store and share patient-related health data across institutions and treatments. The patients themselves decide about sharing the data. So far, this electronic health record is not very widespread.¹⁴ Compared to the electronic patient record, this form of electronic health record is far less regulated: section 68 Social Act No 5 (SGB V) stipulates the funding of projects dealing with these services carried out by third parties (sections 63 et seqq. Social Act No 5 contain provisions on insurance-run pilot projects aimed at an improvement in quality and cost effectiveness of health care). There are no rules determining the right to access to the data, nor data security measures, which has been criticized, arguing that the rules laid down for the electronic health insurance card should be extended to the electronic health record.¹⁵ As there are no specific rules on the use of the data from “personal” electronic health records for research purposes in Social Act No 5, in this case there are no specific data protection rules, so that a recourse to general data protection law is not prohibited. Thus, it would in principle be possible to use the data for research purposes according to general German data protection rules, e.g. if the patient consents to it.

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?

According to the [Act to Adapt Data Protection Law to Regulation \(EU\) 2016/679 and to Implement Directive \(EU\) 2016/680](#) (Gesetz zur Anpassung des Datenschutzrechts an die Verordnung (EU) 2016/679 und zur Umsetzung der Richtlinie (EU) 2016/680 (Datenschutz-Anpassungs- und -Umsetzungsgesetz EU–DSAnpUG-EU)) a new FDPA – BDSG neu (2018) will enter into force on 25.5.2018. On the same date, the old FDPA will cease to be in force. The main aim of the new FDPA is the consolidation of the general data protection law under the terms of the General Data Protection Regulation and the EU Directive (EU) 2016/680¹⁶. As the GDPR will be directly applicable, no national implementation of the legal stipulations of the GDPR is necessary. The new FDPA only transposes regulatory tasks and opening clauses contained in the GDPR,¹⁷ e.g. section 27 of the new FDPA which addresses the processing of special categories of personal data for scientific research and for statistical purposes which the Regulation is one implementation of Art. 9 (2) (j) GDPR.

¹³ Krauskopf, Soziale Krankenversicherung, Pflegeversicherung, 96. EL August 2017, section 68 marginal no. 3.

¹⁴ Kasseler Kommentar Sozialversicherungsrecht/Rothers, 97. EL December 2017, section 68 marginal no. 4.

¹⁵ E.g. by the German Medical Association (Bundesärztekammer - BÄK), see Krüger-Brand, Elektronische Gesundheitsakte: Mehr Schutz nötig, Deutsches Ärzteblatt 2009, A-2458, <https://www.aerzteblatt.de/pdf.asp?id=66988>.

¹⁶ 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.

¹⁷ Greve, H., Das neue Bundesdatenschutzgesetz, NVwZ 2017, p. 737.

On the Länder level there are only drafts out yet.

Regarding the specific acts, the German Parliament has enacted amending laws for the Social Act so far.¹⁸ For the other mentioned acts it remains to be seen whether the German legislative organs will enact changes.

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?

Due to the federal system in Germany, there is a federal supervisory data protection authority (Bundesdatenschutzbeauftragte(r)) and each Land has also a data protection supervisory authority (e.g. in Lower Saxony Die Landesbeauftragte für den Datenschutz Niedersachsen). The competences of these authorities are regulated in the FDPA¹⁹ or in the data protection acts of the respective Land²⁰. In Germany, for research projects the federal data protection authority will rarely come into question as the competent supervisory authority, because it only supervises public institutions of the Federation. In most cases, the supervisory authorities of the Länder are the competent authorities. The supervisory authorities of the Länder supervise public institutions of the respective Land and control the compliance with the data protection law of the respective Land.²¹ The Länder authorities are also in charge of monitoring the implementation of the FDPA and of other data protection provisions governing the automated processing of personal data by private bodies.²² The supervisory authority may order measures to rectify violations during the collection, processing or use of personal data or technical or organizational irregularities caused by private bodies.²³ It may also inform the data subject about breaches of the data protection regulations, open fine procedures in case of infringements of data protection provisions, notify other authorities or prosecution²⁴. In case public institutions are concerned, the data protection authority notifies the competent institution and requires a statement. Imposing fines against public entities is not possible.²⁵

There are register obligations for private bodies. In accordance with section 4d (1) FDPA private controllers prior to putting automated processing procedures into operation, shall register such procedures with the competent supervisory authorities in accordance with section 4e FDPA which provides the content of such notification. There

¹⁸ [BT-Drs. 18/12611 \(German Parliament Document\)](#).

¹⁹ Sections 24 (1-3) FDPA, 38 FDPA.

²⁰ E.g. section 22 Data Protection Act of Lower Saxony.

²¹ E.g. section 22 (1) Data Protection Act of Lower Saxony.

²² E.g. section 38 (6) FDPA in conjunction with section 22 (6) Data Protection Act of Lower Saxony.

²³ Section 38 (5) FDPA.

²⁴ The data protection authorities have a right to demand prosecution.

²⁵ Section 23 Data Protection Act of Lower Saxony.

is an exception to this rule if the controller has appointed a data protection officer. The competent supervisory authority shall keep a register of such automated processing operations which are subject to obligatory registration.²⁶

In so far as automated processing operations involves risks for the rights and liberties of the data subject, according to section 4d FDPA private controllers are subject to examination prior to the beginning of processing (prior checking) as well. Prior checking is to be carried out in particular when special categories of personal data (section 3 (9) FDPA²⁷, e.g. health data) are to be processed. There are exceptions most relevant if the processing is based on the informed consent of the data subject. Prior checking is the responsibility of the data protection officer.²⁸ In cases of doubt, the controller is to refer to the supervisory authority.

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

The established allocation of competences between the Länder and the Federation will prevail under the regime of the GDPR²⁹, see e.g. section 40 of the new FDPA in conjunction with section 22 of the draft of the new Data Protection Act of Lower Saxony. The register obligations according to section 4d of the old FDPA will disappear. Instead Art. 36 GDPR foresees a consultation obligation prior to processing where a data protection impact assessment under Article 35 indicates that the processing would result in a high risk in the absence of measures taken by the controller to mitigate the risk. The prior checking obligation in Art. 4d of the old FDPA turns into an obligatory data protection impact assessment which is now required by Art. 35 GDPR in case the envisaged processing is likely to result in a high risk to the rights and freedoms of the data subjects. According to Art. 37 (1)(c) GDPR the controller and the processor shall designate a data protection officer if the core activities of the controller or the processor consist of processing on a large scale of special categories of data. Additionally paragraph 7 states that the data controller or the processor shall publish the contact details of the data protection officer and communicate them to the supervisory authority.

2. Transposition of Article 8.4 of Directive 95/46

Art. 8.4 of Directive 95/46: “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.”

²⁶ Section 38 (2) FDPA.

²⁷ “Special categories of personal data” means information on a person’s racial or ethnic origin, political opinions, religious or philosophical convictions, union membership, health or sex life.

²⁸ He or she shall carry out prior checking after receiving the list in accordance with section 4g (2) FDPA.

²⁹ Dix, A., in: DS-GVO, BDSG Kommentar (edt. Kühling, J. and Buchner, B.), 2. edt., 2018, section 40 margin number 1.

When transposing Directive 96/46 did your national legislator or supervisory authority make use of the power granted to Member States in Article 8.4 of the Directive? Did the legislator use this provision to insert any additional (i.e. additional to the exceptions listed in the Directive) exemption (to the prohibition to process health data) for the processing of health data for research purposes? If yes, how is such an exemption formulated? Please explain.

a. Transposition of Article 8.4 of Directive 95/46

What are the exceptions to the prohibition of processing sensitive data? Do any of these exceptions address scientific research in the field of health? How is such an exception formulated, and does it set out specific conditions?

There are several implementations of Art. 8 (4) DPD to be found in the German legal system. Which implementation applies depends on the scope of application of the respective law. Most relevant for private bodies is section 28 (6) and (8) FDPA, unless a specific act supersedes the provisions of the FDPA, e.g. a hospital act. For public entities of the Länder either the general data protection provisions of the respective Land or the hospital acts will most likely provide the relevant research exemptions which allow the processing of health data for research purposes. For public entities that are related to the Federation section 13 (2) No 8 and section 14 (2) No 9 FDPA are of relevance. How such an exemption is formulated and what specific conditions are set out will be described in the next subchapter (II.B.).

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?

In Germany, there is no overall specific regime applying to the processing of personal data for health research purposes. There are no additional research exemptions issued by the DPA either, but as described earlier there are a number of laws that implement the Data Protection Directive. A lot of these data protection provisions contain exemption clauses allowing the processing of personal data for research purposes. Before the conditions for the applicability of such clauses are to be evaluated, it must first be ensured that the relevant law has been chosen. While the general data protection provisions entail more general exemption clauses, which nevertheless also apply to health research, the special provisions naturally have a specific relation to the health context, e.g. the hospital acts of the Länder. Not all the exemption clauses can be examined here. The following analysis reflects examples from the FDPA, the Data Protection Act of Lower Saxony as well as a summary of the other Länder general data protection provisions and the Hospital Act of the Land Hamburg.

Section 28 (6) and (8) FDPA

Most relevant for private bodies is section 28 (6) No. 4 and (8) FDPA, unless a specific act supersedes the general provisions of the FDPA. According to this provision, the collection, processing and use of special types of personal data for the controller's own commercial purposes shall be admissible when the data subject has not consented if either the data concerned have evidently been made public by the data subject (No 2) or if this is necessary for the purposes of scientific research, where the scientific interest in carrying out the research project substantially outweighs the data subject's interest in excluding collection, processing and use and the purpose of the research cannot be achieved in any other way or would otherwise necessitate disproportionate effort (No 4). It should be mentioned here that section 28 (6) No 4 FDPA does not enable a retention of the data for general research purposes. Rather, it is necessary that a specific research project is envisaged for which the data is collected and subsequently processed.³⁰ Retention of health data is permitted only by a very limited number of acts, e.g. to a certain degree by the register acts for certain diseases, e.g. cancer registers.³¹ Section 28 (6) No 4 FDPA, as well, only allows in-house-research, which means that the controller must use the data for its own business purposes, not for any third party research task.³²

For the transfer or further processing of special types of personal data section 26 (8) FDPA is relevant, which states inter alia that such data may be transferred or further used only if the above-mentioned requirements of paragraph 6 are met.

Research institutes also must comply with section 40 FDPA (see II.C.)

Sections 4, 9, 10 and 25 Data Protection Act of Lower Saxony (Niedersächsisches Datenschutzgesetz – NDSG)/other Land general data protection acts

The data protection acts of the Länder also foresee rules for processing of personal data for scientific purposes. Examples are the provisions in sections 4, 9, 10 and 25 of the Data Protection Act of Lower Saxony. Section 4 states that the processing of personal data is prohibited unless the data subject has given (written) informed consent, or another legal ground allows the processing. While section 9 of Data Protection Act of Lower Saxony concerns the collection of personal data by public entities, section 10 concerns the use and under which circumstances a change in the purpose of the processing is legitimate.

Section 9 (1) first sentence Data Protection Act of Lower Saxony allows the collection of the personal data if it is necessary for the data controller for the fulfilment of its functions. Pursuing research in the health sector is, for example, such a function of medical university institutions.³³ In the event that the data is not collected directly from the data subject, there are some additional restrictions to the collection. For example, the data may be collected from third parties if they are from generally accessible sources and there are no conflicting legitimate interests on the part of the concerned data subject. They may also be collected from a third party if the collection from the data

³⁰ Schneider, K. U., op. cit., p. 98-99.

³¹ Ibid.

³² Simitis, S., Bundesdatenschutzgesetz (edt. Simitis, S.), 7th ed., 2011, section 28 margin note 309.

³³ Der Landesbeauftragte für den Datenschutz Niedersachsen, Joachim Wahlbrink, Das Niedersächsische Datenschutzgesetz - Gesetzestext und Kommentar, 2014, p. 124.

subject would involve a disproportionate effort and there is no evidence that overriding legitimate interests of the data subject will be affected.

Section 10 of the Data Protection Act of Lower Saxony provides that the data may be used if that is necessary for the data controller to fulfil its public functions and the use is covered by the initial purpose for which the data were collected. Section 10 also provides legal grounds for processing the data for secondary uses. However, section 25 takes precedence over this norm if the secondary use is for a scientific purpose. This section provides that personal data, which have been collected for another purpose or another research project, may be processed for scientific research if there is a written consent of the data subject; or if the nature of the data and the envisaged processing lead to the conclusion that there is no legitimate interest conflicting with the processing for the specific research; or if the public interest in carrying out the research project substantially outweighs the data subject's legitimate interest conflicting with the collection, processing and use of the research. The result of the weighing of interests and the reasoning involved must be protcolled and the data protection officer must be notified. According to the commentary of the law issued by the data protection supervisory authority of Lower Saxony, section 25 of the Data Protection Act of Lower Saxony also applies to special categories of data such as health data.³⁴ Section 25 of the Data Protection Act of Lower Saxony also prescribes for all processing of personal data for scientific research that as soon as the research status permits, the data that allow the identification of the data subject must be stored separately; they have to be destroyed as soon as the purpose of the research allows it; and the data may only be published if the data subject has given his or her consent or this is indispensable for the presentation of research findings on contemporary events. Furthermore, a transfer to a party to whom the Data Protection Act of Lower Saxony does not apply may only take place if the receiving party commits itself to abide by section 25 (3-5) of the DPA of Lower Saxony. Such a transfer must be notified to the data protection authority (Landesbeauftragte für den Datenschutz Niedersachsen).

The other Länder regulate processing of personal health data for research in their general data protection acts in a similar way. Many acts do explicitly require in the context of the weighing of interests that the processing of personal data for the research must be necessary and cannot be pursued in any other reasonable way.³⁵ Some of the specifics with regard to required approval requirements or notification obligations are listed below:

- Approval of weighing of interests by highest state authority in favour of research interest: section 33 (1) Data Protection Act of Hessen³⁶; section 34 (2) Data Protection Act of Mecklenburg-Vorpommern³⁷; section 22 (3) and (4) Data Protection Act of Schleswig-Holstein³⁸

³⁴ Ibid, p. 124-125.

³⁵ e.g. section 36 (1) Data Protection Act of Saxony ([Sächsisches Datenschutzgesetz - SächsDSG](#)); Art. 15 (7) No 7 Data Protection Act of Bavaria ([Bayerisches Datenschutzgesetz - BayDSG](#)); section 28 Data Protection Act of Brandenburg ([Brandenburgisches Datenschutzgesetz - BbgDSG](#)).

³⁶ [Hessisches Datenschutzgesetz - HDSG](#)

³⁷ [Gesetz zum Schutz des Bürgers bei der Verarbeitung seiner Daten \(Landesdatenschutzgesetz - DSG M-V\)](#)

³⁸ Notification of approval to data protection authority required; [Schleswig-Holsteinisches Gesetz](#)

- Notification of transfer to third parties (to whom data protection act does not apply) to the data protection authority: section 27 (2) Data Protection Act of Hamburg³⁹; section 34 (2) Data Protection Act of Mecklenburg-Vorpommern⁴⁰; section 28 (5) Data Protection Act of Nordrhein-Westfalen⁴¹; section 30 (7) Data Protection Act of Saarland⁴²; section 25 (2) Data Protection Act of Thüringen⁴³
- approval by the highest state authority of the transfer: section 30 (1) Data Protection Act of Berlin⁴⁴; section 30 (3) Data Protection Act of Saarland⁴⁵.

sections 12, 12a Hospital Act of Hamburg

One example for a specific law that may have to be considered are sections 12 and 12a of the [Hospital Act of Hamburg](#). In contrast to Hamburg, Lower Saxony does not have special data protection provisions in its Hospital Act, which is why in Lower Saxony for privately owned hospitals the FDPA becomes relevant and for public entities the Data Protection Act of Lower Saxony needs to be considered. According to section 12 of the Hospital Act of Hamburg, physicians are allowed to process patient data for their own research if they do not infringe legitimate interests of the patients. Patient data may also be transferred for specific research projects to third parties outside of the hospital if either the data cannot be attributed to a specific person or, if the attribution to a specific person is required by the research purpose, the patient has consented. In the latter situation, a transfer may also be allowed in the absence of consent, if such consent cannot be obtained with reasonable means, provided this is necessary for the purposes of the specific scientific research project and the public interest in carrying out the research project substantially outweighs the legitimate interest of the data subject. In such cases, the personal data must further undergo pseudonymisation and the identifying data must be stored separately. The treatment sector and the research sector must be organisationally separated and the data must be anonymized as soon as the research purpose allows it, at the latest when the research project is finished, if the data cannot be deleted for specific reasons. In case it is necessary to store the data in personal form for internal scientific monitoring, data can be stored in pseudonymised form, but no longer than 10 years after the conclusion of the research project.

Section 12a of the Hospital Act of Hamburg concerns the collection of specimens and patient data for scientific research. In contrast to section 12 of the Act, the purpose may be more general and not limited to a specific research

zum Schutz personenbezogener Informationen (Landesdatenschutzgesetz - LDSG -).

³⁹ Hamburgisches Datenschutzgesetz (HmbDSG)

⁴⁰ Gesetz zum Schutz des Bürgers bei der Verarbeitung seiner Daten (Landesdatenschutzgesetz - DSG M-V)

⁴¹ Datenschutzgesetz Nordrhein-Westfalen - DSG NRW

⁴² Saarländisches Gesetz zum Schutz personenbezogener Daten (Saarländisches Datenschutzgesetz - SDSG)

⁴³ Thüringer Datenschutzgesetz (ThürDSG)

⁴⁴ Gesetz zum Schutz personenbezogener Daten in der Berliner Verwaltung

(Berliner Datenschutzgesetz - BlnDSG)

⁴⁵ Notification of approval to data protection authority required; Saarländisches Gesetz zum Schutz personenbezogener Daten (Saarländisches Datenschutzgesetz - SDSG).

project. The specimens and data can be collected if patients have been informed about the purpose and processing possibilities and consented to the collection in question. The same applies to earlier collected samples and data. If the purpose of the collection requires the attribution to specific persons, specimen and data have to undergo pseudonymisation. If the specimens and data are used/transferred for a specific research project, data must be anonymized or if the research purpose requires attribution to specific persons pseudonymized. In case of genetic research, the controller must consider the protection of the data subject requires an independent data custodian to be charged with the pseudonymisation of the patient data. The establishment of such a biobank or database must be notified to the competent supervisory authority, which would be the Hamburgische Beauftragte für Datenschutz und Informationsfreiheit. After five years the notification must be renewed and the further storage of the data and specimen must be justified.

The majority of the other Länder also have special provisions for data protection in their hospital acts which may become of relevance in the context of processing patient data.

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

There are exemptions for researchers laid down in the relevant legislation, e.g. researchers are exempted from notification obligations according to section 33 (1) FDPA if the storage or transfer of the data is necessary for the purposes of scientific research, and notification would require disproportionate effort (section 33 (2) first sentence No 5 FDPA). In such cases there shall also be no obligation to provide information at the request of the data subject (section 34 (7) FDPA). Data which has been blocked according to section 35 (3 or 4) FDPA may only be transferred or used without the data subject's consent if this is indispensable for scientific purposes.

The Data Protection Act of Lower Saxony, for example, also provides that the right of access can be denied if this would hinder the authority from duly performing their other tasks (section 16 (4) No 1 Data Protection Act of Lower Saxony).

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?

First of all, the exemption clauses – may it be the general data protection acts or the special provisions – all reflect a weighing of interests and that the research substantially outweighs the legitimate data subject's interest in not processing the data for the research. In order to achieve that it is also necessary that the personal data is efficiently protected and that the data subject does not suffer any detriment from any misuse of the data. Especially the special provisions in the hospital acts contain detailed conditions the controller must comply with when processing data for research, such as anonymization or pseudonymisation of the data if the attribution to the specific person is required by the research purpose (see II.B.). But also the general data protection acts can contain specific provisions that researchers must implement (see II.B.) Again, all these provisions reflect general data protection principles,

especially the principle of data minimisation, and although more general clauses may not entail specific safeguards, these are implicitly required. For the FDPA section 40 lays down explicit additional safeguards, which must be considered by research institutes.⁴⁶ Accordingly, personal data collected or stored for scientific research purposes may be processed or used only for such purposes. The purpose for the use of the data is therefore restricted only to research. Also, the personal data shall be rendered anonymous as soon as the research purpose permits this. Until such time, the characteristics enabling information concerning personal or material circumstances to be attributed to an identified or identifiable individual shall be stored separately. They may be combined with the information only to the extent required by the research purpose. Section 40 FDPA also sets out the conditions for publishing personal data by bodies conducting research. They shall only publish the data if the data subject has consented or if this is indispensable for the presentation of research findings on contemporary events.

In general, the data protection acts provide provisions that require data controllers and data processors to take the technical and organizational measures necessary to ensure the implementation of the provisions of the applicable data protection acts. Measures shall be required only if the effort involved is reasonable in relation to the desired level of protection. The FDPA provides in its Annex⁴⁷ a number of measures to protect personal data.

⁴⁶ Section 40 FDPA applies to private and public research institutes in the scope of application of the FDPA; research institutes in the sense of this provision are entities whose tasks and structures are oriented towards research (Simitis, in: Simitis (section 40 margin note 17, 29).

⁴⁷ “Where personal data are processed or used automatically, the internal organization of authorities or enterprises is to be arranged in such a way that it meets the specific requirements of data protection. In particular, measures suited to the type of personal data or data categories to be protected shall be taken,

1. to prevent unauthorized persons from gaining access to data processing systems with which personal data are processed or used (access control),
2. to prevent data processing systems from being used without authorization (access control),
3. to ensure that persons entitled to use a data processing system have access only to the data to which they have a right of access, and that personal data cannot be read, copied, modified or removed without authorization in the course of processing or use and after storage (access control),
4. to ensure that personal data cannot be read, copied, modified or removed without authorization during electronic transmission or transport, and that it is possible to check and establish to which bodies the transfer of personal data by means of data transmission facilities is envisaged (transmission control),
5. to ensure that it is possible to check and establish whether and by whom personal data have been input into data processing systems, modified or removed (input control),
6. to ensure that, in the case of commissioned processing of personal data, the data are processed strictly in accordance with the instructions of the principal (job control),
7. to ensure that personal data are protected from accidental destruction or loss (availability control),
8. to ensure that data collected for different purposes can be processed separately.

One measure in accordance with the second sentence Nos. 2 to 4 is in particular the use of the latest encryption procedures.”

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?

(i) Professional secrecy

Criminal Code

The provision section 203 (1) of the [Strafgesetzbuch - StGB](#), which is the [German Criminal Code](#), sanctions breaches of medical confidentiality. According to this provision, inter alia a physician, dentist, veterinarian, pharmacist or member of another healthcare profession which requires state-regulated education for engaging in the profession or to use the professional title as well as a professional psychologist, who unlawfully disclosed a secret of another which was made known to him or her in his or her capacity as a physician, shall be liable to imprisonment or a fine. The term secret is very widely interpreted and means any factual information that is only known to a limited number of people and which is in the interest of the patient to remain a secret. When it comes to the physician patient relationship any patient data falls in the secret category and must not be unlawfully disclosed. Only internal notice of the data by treating personnel is not to be seen as criminal disclosure.⁴⁸ Physicians that are not taking part in the treatment of the particular patient are to be considered as third persons and disclosure to them is principally forbidden.⁴⁹ Criminal liability is ruled out if the data have been anonymized⁵⁰ or if the data subject has given his consent to the disclosure⁵¹. In case the data is effectively pseudonymised and the pseudonymisation key stays with the physician, the disclosure of patient data to a third party is not to be considered as a criminal act.⁵² However, the mere fact that the patient data will be used for research and eventually for the common good or the public interest does not justify the breach of medical secrecy.⁵³ Provisions that allow the processing of personal data for research only exclude criminal liability if they also explicitly refer to the protected relationship between physician and patient.⁵⁴ Professional secrecy obligations should always be considered if treatment data is further processed for research purposes, especially if it is transferred to third parties.

⁴⁸ Schneider, U. K., op. cit., p. 47; Ciernak, J. and Niehaus, H., Münchener Kommentar, 3rd ed., 2017, section 203 StGB margin note 53.; section 203 (3) StGB permits disclosure to helping staff or other persons that are engaged in the professional activity of the person subject to professional confidentiality if it is required.

⁴⁹ Ciernak, J. and Niehaus, H., Münchener Kommentar, 3rd ed., 2017, section 203 StGB margin note 52.

⁵⁰ Schneider, K. U., op. cit., p. 47-48.

⁵¹ Kühn, H. C., The Implementation of the Data Protection Directive 95/46/EC in Germany, Implementation of the Data Protection Directive in Relation to Medical Research in Europe, 2004, p. 124.

⁵² Cornelius, K.; Die Bereitstellung humaner Alt-Bioproben durch eine Biobank zu Zwecken der medizinischen Genomforschung, MedR 2017, p. 18; Ciernak, J. and Niehaus, H., Münchener Kommentar, 3rd ed., 2017, section 203 StGB margin note 51.

⁵³ Kühn, H. C., op. cit., p. 124.

⁵⁴ Schneider, K. U., op. cit., p. 51.

Professional law

In each Land physicians underlying professional law (Berufsordnung), e.g. in Lower Saxony the [Berufsordnung der Ärztekammer Niedersachsen](#) applies. These laws entail similar provisions concerning medical secrecy obligations of the physician, e.g. section 9 Berufsordnung der Ärztekammer Niedersachsen.

(ii) *Express consent for specific data*

Genetic Diagnostic Act

The Genetic Diagnostic Act ([Gendiagnostikgesetz - GenDG](#)), which applies when the data have been initially collected also for treatment purposes, sets a number of additional requirements, e.g. regarding the informed consent process as there are specific counselling obligations and data may only be used for research if the data subject consented to it (see I. A.). Otherwise the research may not be proceeded, neither on the basis of a research exemption.

Medicinal Products Act

The [Medicinal Products Act \(Arzneimittelgesetz – AMG\)](#) also sets specific rules for the processing of personal data in the context of clinical trials. For example, the processing is only allowed if the data subject gave consent. For the further processing of the data this shall also apply.⁵⁵ This will also be the case when the Clinical Trials Regulation will enter into force.⁵⁶

(iii) *Specific provisions for deceased data subjects*

Post-mortem protection of personal data is inconsistently regulated in Germany. The data protection provisions in the hospital acts often also apply to data from deceased persons.⁵⁷ In those cases for pursuing research with such data, the data protection regulations must be complied with. The Data Protection Act of the Land of Berlin⁵⁸ states that data of deceased is protected as long as interests of the deceased worthy of protection may be compromised. The FDPA does not apply to data from deceased individuals.⁵⁹ However, even if the relevant data protection regulation would not apply to data that relate to deceased persons, the deceased remains at the least protected by the constitutional overall right of respect of the person derived from the fundamental right of human dignity under Article 1(1) of the German Constitution also known as the post-mortem personality right (postmortales Persönlichkeitsrecht). This right protects the public image of the deceased.⁶⁰ However, as memories of the deceased fade the post-mortem personality right also weakens over time⁶¹ and the right does not protect personal sentiments

⁵⁵ Schneider, K. U., op. cit., p. 69.

⁵⁶ Art. 28 (2), Recital 29 Regulation (EU) No 536/2014 of the European Parliament and of the Council of 16 April 2014 on clinical trials on medicinal products for human use and repealing Directive 2001/20 /EC.

⁵⁷ E.g. section 7 (1) [Hospital Act of the Land Hamburg](#), section 28 (1) [Hospital Act of the Land Brandenburg](#).

⁵⁸ Section 4 (1) Data Protection Act of the Land Berlin ([Berliner Datenschutzgesetz - BlnDSG](#)).

⁵⁹ Hänold, S. et. al., Legal perspectives on post-mortem use of biomaterial and data for research: a focus on the German situation, EJHL 2017, p. 321-323; Cornelius, K.; Die Bereitstellung humaner Alt-Bioproben durch eine Biobank zu Zwecken der medizinischen Genomforschung, MedR 2017, p. 18.

⁶⁰ Grundgesetz-Kommentar 2015, Article 1 margin note 58; Cornelius, K.; op. cit., p. 18.

⁶¹ Federal Constitutional Court, Judgement 30, 173, 24.02.1971.

of the deceased or past acts of self-determination such as decisions regarding the use of samples and data made during the informed consent process⁶². On that note, only when the data is made public in an identifying form, and if the data contains sensitive information with the potential to harm the deceased's reputation (e.g. in case of genetic defects or an HIV infection), the post-mortem personality right could be infringed.⁶³ Consequently, data of a deceased person may be used for research if precautionary measures regarding the confidentiality of the data and material are implemented.⁶⁴ In how far decisions made at lifetime by the deceased individual shall have a legal effect after death, is unclear. It has been argued that the right to protection of the personality according to Article 2(1) in conjunction with Article 1(1) of the German Constitution, which protects privacy and self-determination, should continue to have an effect when the concerned person has died.⁶⁵

The professional secrecy obligations entailed in [section 203 \(1\) of the](#) Criminal code and in the professional laws do not end with the death of the patient.⁶⁶

(iv) Specific provisions for minors or persons subject to guardianship

The FDPA and data protection acts of the Länder do not determine when a minor can give a valid informed consent to processing of his/her personal data. It depends on the cognitive faculty of the child or adolescent whether consent is valid or not.⁶⁷ As far as minors can judge the necessity and impact of medicinal treatment and their consent is required for carrying out the treatment, they shall also be able to determine upon the use of their personal data.⁶⁸ As an approximate benchmark, the age of 14 can be considered.⁶⁹ When the minor cannot give consent himself or herself, the parents/legal guardians are usually entitled to give consent for their children. Often the actual will of the child is still considered in the consent procedure. The research exemptions in the general data protection acts of the federation or the Länder do not mention special requirements for the processing of personal data of minors. Whether the minor is to be informed about data processing of his data or not depends on his cognitive faculty to

⁶² See also Spilker, B., Postmortaler Datenschutz, DöV 2015, p. 54.

⁶³ Hänold et al., op. cit., p. 322.

⁶⁴ Ibid.

⁶⁵ Spilker, B., Postmortaler Datenschutz, DöV 2015, pp. 54-49.

⁶⁶ Lenckner, T. and Eisele, J., Schönke/Schröder Strafgesetzbuch Kommentar, 29 ed., 2014, section 203 StGB margin note 70; section 9 (1) [Berufsordnung der Ärztekammer Niedersachsen](#).

⁶⁷ Gola et al., Gola/Schomerus, BDSG, 12th ed. 2015, margin note 2a.

⁶⁸ Simitis, S., op. cit., section 4a BDSG, margin number 23.

⁶⁹ Metschke, R. and Wellbrock, R.; Datenschutz in Wissenschaft und Forschung (edt.: Berliner Beauftragter für Datenschutz und Informationsfreiheit and Hessischer Datenschutzbeauftragter), https://www.datenschutz.hessen.de/download.php?download_ID=147, p. 26.

understand the information.⁷⁰ The information must be presented appropriately to make the information understandable for the minor.⁷¹ The execution of data subjects rights also depends on his or her cognitive faculty.⁷²

There are special restrictions for the participation of minors in clinical trials according to section 40 (4) [Medicinal Products Act \(Arzneimittelgesetz – AMG\)](#), which have effect on which minors can participate in the trial in the first place.

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

Under the legal regime of the FDPA, principally, the data subject has the right of access and the right to correction, erasure and blocking. According to section 6 (1) FDPA, these rights may not be excluded or restricted by a legal transaction.

The FDPA distinguishes between the rights of the data subjects against private bodies and public entities as data controllers. At first we will look at the rights against private bodies.

Private bodies

There are no special rights granted to the data subject by section 40 FDPA, which is the special provision on the processing and use of personal data by (non-public) research institutions.

Therefore, the general provisions on data subject’s rights are applicable.

Notification

For private entities, section 33 (1) first sentence FDPA stipulates that if personal data are stored for the first time for one’s own purposes without the data subject’s knowledge, the data subject shall be notified of such storage, the type of data, the purposes of collection, processing or use and the identity of the controller. If personal data are stored commercially without the data subject’s knowledge for the purpose of transfer, the data subject shall be notified of their initial transfer and of the type of data transferred (section 33 (1) second sentence FDPA). Additionally, in these cases the data subject shall be notified of the categories of recipients, in so far as he or she cannot be expected to assume transfer to such recipients according to the circumstances of the individual case concerned (third sentence). There are exemptions to the requirement of notification, which are enlisted in section 33 (2) first sentence FDPA. For example, notification is not required if storage or transfer is necessary for the purposes of scientific research and notification would require disproportionate effort (No 5). Other exemptions are if the data subject has received knowledge by other means of the storage or transfer of the data (No 1), or if the data must be kept secret in accordance with a legal provision or by virtue of their nature, in particular on account of an overriding legal interest of a third party (No 3), or if the law expressly provides for such storage or transfer (No 4). In all these cases except for section 33 (2) first sentence No 1, the controller shall stipulate in writing under what conditions notification shall not be provided.

⁷⁰ Jandt, S. and Roßnagel, A., Soziale Netzwerke für Kinder und Jugendliche – Besteht ein ausreichender Datenschutz?, MMR 2011, pp. 640-641.

⁷¹ Ibid.

⁷² Ibid.

Provision of information to the data subject

According to section 34 FDPA, the data subject has the right to request information on stored data about the data subject, also where they refer to the origin of these data, on the recipient or type of recipients to whom the data are provided, and the reason for storage. The data controller shall provide this information at the request of the data subject, who shall provide a detailed description of the type of personal data he or she would like information about.

According to section 34 (7) FDPA researchers are exempted from the obligation to provide the requested information if the storage or transfer of the data is necessary for the purposes of scientific research and notification would require disproportionate effort .

Correction, erasure and blocking of data

Section 35 (1) FDPA stipulates that inaccurate personal data shall be corrected. There are cases in which personal data in filing systems shall be erased: if their storage is inadmissible, or if they concern information i.a. on health, and the controller is unable to prove their accuracy (section 35 (2) second sentence FDPA). Instead of erasure, personal data shall be blocked where (among others) there is reason to assume that erasure would impair legitimate interests of the data subject, or where erasure is not possible or is only possible with disproportionate effort due to the specific type of storage (section 35 (3) FDPA).

Public entities

Parallel provisions can be found if the data are collected by public bodies related to the Federation: if the data is collected without the data subject's knowledge, information to the data subject of storage, the controller's entity and of the purposes of collection, processing or use also shall be provided (notification, section 19a FDPA). The data subject is also to be notified of the recipients or categories of recipients of data, except where he/she must expect transfer to such recipients. When transfer is envisaged, notification is to be provided at the time of the first transfer at the latest. Furthermore, at the data subject's request, information shall be provided by public entities on stored data concerning him or her, including any reference in them to their origin, the recipients or categories of recipients to whom the data are transmitted, and the purpose of storage (provision of information to the data subject, section 19 FDPA). The right to erasure and blocking of data processed by public bodies is laid down in section 20 (1)-(4) and (6)-(9) FDPA.

In section 20 (7) No 1 FDPA, there is a specific allowance to transfer or use blocked data without the consent of the data subject: this may be done i.a. if it is indispensable for scientific purposes, or in other cases in which there are overriding interests of the controller of the data or of a third party (section 20 (7) No 1 FDPA).

Additionally, for data processed by public bodies, the data subject has the right of objection according to section 20 (5) FDPA, and the right to appeal to the Federal Commissioner for Data Protection and Freedom of Information if he or she believes that his or her rights have been infringed through the collection, processing or use of his or her personal data (section 21 FDPA).

However, these rules only apply to the collection, processing or use of personal data by public bodies of the Federation.

On the Länder level, which are relevant for public entities of the Länder, the general data protection acts also entail provisions regarding data subjects rights. In the Data Protection Act of Lower Saxony, for instance, these can be found in sections 9 and 16 - 20. In case personal data is collected from the data subject, he or she must be informed about the purpose of the processing and if the collection is based on a legal ground the legal provision also must be part of the information (section 9 (2) Data Protection Act of Lower Saxony). Additionally, data subjects have the right to request information with regard to which information is stored about them, the purpose of the processing and what is the legal basis for the processing of their personal data (section 16 Data Protection Act of Lower Saxony). They are as well entitled to oppose the processing of their personal data for legitimate personal reasons (section 17 a Data Protection Act of Lower Saxony).

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?

The general penalty regulations apply.

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?

It has been described in the subsections above that in Germany a subset of laws have to be considered when personal health data is processed for research purposes (I.A.; II.B.). In case special regulations, for example, data protection provisions laid down in hospital acts apply to the individual case, these supersede the data protection provisions in the general data protection acts. Otherwise, if no special provisions are in place, the processing must be in compliance with the applicable general data protection regime of either the FDPA or the relevant data protection act of the relevant Bundesland. Examples have been given in II.B.

Eventually, section 4d FDPA (see I.C.) applies.

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

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

The notion of further processing has been implemented in the respective data protection provisions. The presented examples in II.B. show this very well.

While, for example, section 28 (6) No 4 FDPA refers to the first collection and the subsequent processing in compliance with the original purpose, section 26 (8) FDPA refers to a change of the purpose and stipulates the conditions under which a change in the purpose of the processing is permitted. Since section 28 (8) FDPA refers back to section 28 (6) FDPA, the legal conditions for further processing the data for research do not vary from section 28 (6) No 4 FDPA. However, the change of the purpose may be a fact to be considered in the weighing of interests required by section 28 (8) in conjunction with section 28 (6) FDPA.

With respect to the data protection act of Lower Saxony, it also has been shown that the first collection and subsequent processing is based on another legal basis (sections 4, 9 Data Protection Act of Lower Saxony) than the further processing of the personal data for a new research purpose or a different research project (section 25 Data Protection Act of Lower Saxony). The further processing can be based on the written consent or a weighing of interests must be in favour of the researcher's interest in pursuing the research, which will be the case either if the nature of the data and the envisaged processing lead to the conclusion that there is no legitimate interest against the processing for the specific research; or if the public interest in carrying out the research project substantially outweighs the data subject's interest in excluding collection, processing and use for the purpose of the research. The result of the weighing of interests and its reasoning must be protocolled and the data protection officer must be notified. Section 25 also prescribes for all processing of personal data for scientific research that, as soon as the research status permits it, the data that allow the identification of the data subject must be stored separately; they have to be destroyed as soon as the purpose of the research allows it. For publishing of the data and transfer to third parties, section 25 also sets specific rules (see II.B.)

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

The general data protection acts do allow a change in the purpose, but the respective provisions set out specific conditions for such a change (see section above and II.B.).

Additionally, section 40 FDPA (see II.B.) also must be considered with the consequence that the data once used in the research context may not be used again outside the research context. Section 39 FDPA also limits the possibilities for further use. Accordingly, personal data, which are subject to professional or special official secrecy and which have been supplied by the body bound to secrecy in the performance of its professional or official duties, may be processed or used by the controller of the filing system only for the purpose for which they were received. In the event of transfer to a private body, the body bound to secrecy must give its consent. This means in case the data have been supplied for treatment purposes, they cannot be used for research by the receiving party unless the change of purpose is permitted by special legislation.

Special acts may also foresee restrictions, e.g. the Genetics Diagnostic Act or the Medicinal Products act, both requiring the informed consent for further processing (I.A.). The hospital acts may also set up specific conditions for the further processing of patient data for research purposes.⁷³

⁷³ A good overview is presented in Schneider, U. K., op. cit., p. 87-89.

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

In case of further processing by the same controller no additional notification to the data subject is required. According to the FDPA, the data subject must be notified only when the data are stored for the first time. It does not state that the change of the purpose requires an additional notification.⁷⁴ An extension of the notification obligation through an analogous application of the notification obligations is partly opined at least where a considerable change in the purpose of the processing is present.⁷⁵ However, other scholars reject this view because the law does not foresee such an additional notification obligation and section 33 FDPA as such is a very differentiated norm and a gap in the law which is a precondition for a legal analogy is not to be found.⁷⁶ The jurisdiction neither has extended section 33 FDPA in case of changes of the purpose of the processing.⁷⁷

In case a transfer of data to another data controller is involved, the new data controller must inform the data subject about the first storage of the data as has been described in II.C.

The other data subjects rights also apply in the case of further processing, some of them provide exemptions for the research context if certain conditions are met (see elaborations in II.C.).

Similar to the FDPA the data protection act for Lower Saxony neither provides additional rights in case of further processing for a new purpose. However, the above made elaborations may be considered.

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

There are no deviations from the previous elaborations.

⁷⁴ Thüsing, G., and Pötters, S. ; Beschäftigtendatenschutz und Compliance, 2nd ed., 2014, Section 18. Informations und Organisationspflichten bei der Datenverarbeitung, II.1.3.§ 33 BDSG - Informationspflicht bei erstmaliger Speicherung, margin number 18.

⁷⁵ Gola, P., et al., *Gola/Schomerus*, Bundesdatenschutzgesetz - Kommentar, 12th ed., 2015, § 33 margin number 16.

⁷⁶ Thüsing, G., and Pötters, S., op. cit.

⁷⁷ Ibid.

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

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

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

As stated earlier (I.B.), the existent FDPA and the data protection acts of the Länder will be replaced by new acts. The [new FDPA](#) has been adopted already. At the Länder level only drafts have been published to date.

The German legislature enacted an exemption according to Art 9 (2)(j) GDPR in the new FDPA in section 27, which allows the processing of special categories of data under stipulated conditions. Section 27 of the new FDPA now applies to private bodies and public entities of the Federation⁷⁸, so the former differentiation between private bodies and public bodies is omitted.⁷⁹ Section 27 FDPA will therefore be of most relevance when it comes to the processing of personal data for research purposes by private bodies, unless a more specific regulation applies (see next paragraph). However, for research entities allocated to the Länder, such as for example the majority of German universities, the relevant Land data protection provisions will apply.⁸⁰

Specific laws, such as the Social Act, Medicinal Products Act or the Genetics Diagnostic Acts, cancer registration laws or hospital acts (which have been looked at in I.A.), will continue to prevail over the general data protection acts of the Federation or the Länder, so if the scope of application of these special acts is extended, those must be considered.⁸¹ Whether those specific acts will undergo reform remains to be seen. For now, only the Social Act has been adapted (I.B.). The legal situation regarding processing personal health data for research will continue to be something of a patchwork quilt.

Implementation of Art. 9 (2)(j) GDPR on the federal level - The new FDPA

⁷⁸ The scope of application is laid down in section 1 (1) FDPA, it also covers public bodies of the Länder if where data protection is not governed by Land law and where they carry out federal law or act in the capacity of judicial bodies in matters other than administrative matters.

⁷⁹ Buchner, B. and Tinnefeld, M.-T., in: DS-GVO, BDSG Kommentar (edt. Kühling, J. and Buchner, B.), 2. edt. 2018, section 27 margin number 6.

⁸⁰ We will introduce one example for the Land Lower Saxony in more detail below.

⁸¹ Buchner, B. and Tinnefeld, M.-T., in: DS-GVO, BDSG Kommentar (edt. Kühling, J. and Buchner, B.), 2. edt. 2018, section 27 margin number 26.

Section 27 of the new FDPA states that the processing of special categories of personal data⁸² shall be permitted also without consent for scientific or historical research purposes or statistical purposes, if such processing is necessary for these purposes and the interests of the controller in processing substantially outweigh those of the data subject in not processing the data. Section 27 of the new FDPA does not explicitly require anymore that the research is done for the controller's own commercial purposes. It remains uncertain in how far data processing for broader research purposes is also covered by section 27 of the new FDPA, as the wording of the regulation is ambiguous and leaves room for interpretation.

According to the section, the controller shall take appropriate and specific measures to safeguard the interests of the data subject. A reference to section 22 (2), second sentence is made which makes clear that for evaluating what measures are appropriate the state of the art, the cost of implementation and the nature, scope, context and purposes of processing as well as the risks for the data subject posed by the processing are to be taken into account by the controller. Section 22 (2) also mentions specific safeguards controllers may use.⁸³ Section 27 (3) of the new FDPA requires that additionally the personal data shall be rendered anonymous as soon as the research or statistical purpose allows, unless this conflicts with legitimate interests of the data subject. Until such time, the characteristics enabling information concerning personal or material circumstances to be attributed to an identified or identifiable individual shall be stored separately. They may be combined with the information only to the extent required by the research or statistical purpose. Paragraph 4 of section 27 of the new FDPA contains provisions for publishing the data. Accordingly, publishing is only allowed if the data subject has consented or if doing so is indispensable for the presentation of research findings on contemporary events.

Section 27 (2) of the new FDPA concerns the rights of the data subjects (see IV.B.).

⁸² For other types of personal data Art. 6 GDPR must be considered.

⁸³ *Taking into account these measures may include in particular the following:*

1. *technical organizational measures to ensure that processing complies with Regulation (EU) 2016/679;*
2. *measures to ensure that it is subsequently possible to verify and establish whether and by whom personal data were input, altered or removed;*
3. *measures to increase awareness of staff involved in processing operations;*
4. *designation of a data protection officer;*
5. *restrictions on access to personal data within the controller and by processors;*
6. *the pseudonymization of personal data;*
7. *the encryption of personal data;*
8. *measures to ensure the ability, confidentiality, integrity, availability and resilience of processing systems and services related to the processing of personal data, including the ability to rapidly restore availability and access in the event of a physical or technical incident;*
9. *a process for regularly testing, assessing and evaluating the effectiveness of technical and organizational measures for ensuring the security of the processing;*
10. *specific rules of procedure to ensure compliance with this Act and with Regulation (EU) 2016/679 in the event of transfer or processing for other purposes.*



Partners

Section 28 of the new FDPA concerns the processing of special categories of personal data for archiving purposes in the public interest.

Implementation of Art. 9 (2)(j) GDPR on the Länder level - Draft of the Data Protection Act of Lower Saxony

On the Länder level new data protection acts will be enacted. For the Data Protection Act of Lower Saxony the draft has been published. The Act will apply, like the previous Data Protection Act of Lower Saxony, to public bodies in Lower Saxony, e.g. the universities situated in Lower Saxony.⁸⁴ For the processing of special categories of data for research purposes, section 13 is relevant. There it is stated that public bodies may process personal data, including that mentioned in Art. 9 (1) GDPR, for a specific research project or transfer such data for this reason to other bodies if the nature of the data and the envisaged processing lead to the conclusion that there is no legitimate interest on the part of the data subject against the processing for the specific research; or the public interest in carrying out the research project substantially outweighs the legitimate data subject's interest in excluding the processing of his or her data for the research purpose. The result of the weighing of interests and its reasoning must be protocolled and the data protection officer must be notified.

Additionally, section 13 (2) of the draft Act provides that as soon as the research purpose allows it, the data must be anonymized. Until then, the data that allow the identification of the data subject, must be stored separately and may only be merged with the related data if the research purpose requires so.

According to section 13 (3) of the draft Act data may only be published if the data subject has given his or her consent or this is indispensable for the presentation of research findings on contemporary events.

A transfer to a party to whom the Data Protection Act of Lower Saxony does not apply may only happen if the receiving party undertakes to use the data only for a prior determined specific research project; to adhere to section 13 (1-3) of the Data Protection Act of Lower Saxony, as well as to implement safeguards pursuant to section 17 of the draft or equivalent measures. Such a transfer must be notified to the supervisory authority of Lower Saxony.

Section 17 of the draft of the Data Protection Act of Lower Saxony lists measures that have to be implemented by data controllers or data processors if special categories of data are processed. The following measures contained in the list are mandatory:

- measures to ensure that it is subsequently possible to verify and establish whether and by whom personal data were processed;
- restrictions on access to personal data according to the necessity to process the personal data and documentation of these access rights;
- data protection awareness-raising among persons who have access to the personal data.

⁸⁴ Section 1 of the draft of the new Data Protection Act of Lower Saxony.

As far as it is necessary for the protection of special categories of personal data the data controller or data processors have to implement additional measures. These measures may include in particular the following:

- securing that the data will only be released if the four-eyes-principle is followed;
- securing that data can only be accessed after two-factor authentication;
- securing that the electronic transfer of personal data only is pursued if an end-to-end-encryption is in place;
- securing that in a networked system the personal data will only be stored if encrypted;
- securing through a design incorporating backup energy supply systems and data transmission facilities that loss of data is prevented;
- securing that the data cannot be unauthorizedly altered and data integrity is secured, e.g. by using electronic signatures;
- training of persons that have access to the data.

Which measures are required depends upon the state of the art, the costs of implementation, the type and extent, the conditions and the purpose of the processing as well as risks for the data subject posed by the processing.

Implementation of Art. 9 (2)(j) GDPR on the Länder level - The situation in the other Länder

The general data protection acts of the other Länder are also undergoing legislation reform. So far only drafts have been released. The implementation of Art. 9 (2)(j) GDPR in the other Länder is similar to the provisions in the draft of the Data Protection Act of Lower Saxony, but there are differences, e.g. some of the Länder provisions, as with the new FDPA, require that the interest in pursuing the research *substantially* outweighs those of the data subject in not processing the data, e.g. the drafts of the new data protection act for Baden-Württemberg⁸⁵ or Bavaria⁸⁶. In contrast, in Lower Saxony and Berlin⁸⁷ it is sufficient if the interest in pursuing the research outweighs the contradicting interests of the data subject. The majority of the drafts also explicitly require that the research cannot be (reasonably) achieved by other means, see e.g. the draft Data Protection Acts of Brandenburg⁸⁸, Baden-

⁸⁵ [Gesetz zur Anpassung des allgemeinen Datenschutzrechts und sonstiger Vorschriften an die Verordnung \(EU\) 2016/679.](#)

⁸⁶ [Gesetzentwurf der Staatsregierung für ein Bayerisches Datenschutzgesetz, LT-Drs 17/19628](#)

⁸⁷ [Gesetz zur Anpassung des Allgemeinen Datenschutzrechts an die Verordnung \(EU\) 2016/679 und zur Umsetzung der Richtlinie \(EU\) 2016/680, LT-Drs 6/7365](#)

⁸⁸ [Gesetz zur Anpassung des Allgemeinen Datenschutzrechts an die Verordnung \(EU\) 2016/679 und zur Umsetzung der Richtlinie \(EU\) 2016/680, LT-Drs 6/7365](#)

Württemberg and Hamburg⁸⁹, whereas the draft Act of Lower Saxony omits this condition. The drafts also differ with respect to the aspect whether only specific research projects fall under the exemption clause. *While, for example in Lower Saxony*, Hamburg and Mecklenburg-Vorpommern⁹⁰ only processing of (special categories of) personal data for specific *research projects* fall in the scope of the research exemptions, the provisions of the drafts from Baden-Württemberg, Bremen⁹¹ and Hessen⁹² may also cover processing for *research purposes* in more general forms.

The requirement for approvals of the highest state authorities has not been taken up in the drafts, and nor has the notification obligation to data protection authorities. However, there may be a notification obligation according to Art. 36 GDPR (IV.B.).

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

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

As stated earlier (I.C.) the prior checking obligation by the data protection officer in section 4d of the old FDPA, mainly of relevance for private bodies⁹³, turns into an obligatory data protection impact assessment which is now required by Art. 35 GDPR for public and private data controllers in case the envisaged processing is likely to result in a high risk to the rights and freedoms of the data subjects. The register obligations according to section 4d of the old FDPA, also mainly of relevance for private bodies⁹⁴, will be replaced by a consultation obligation according to Art. 36 GDPR, which as well applies to public and private data controllers. Art. 36 GDPR provides the obligatory consultation of the supervisory authority prior to processing where a data protection impact assessment under Article 35 indicates that the processing would result in a high risk in the absence of measures taken by the controller to mitigate the risk. Also instead of the notification obligations according to the former general data protection acts of the

⁸⁹ Entwurf eines Gesetzes zur Anpassung des Hamburgischen Datenschutzgesetzes sowie weiterer Vorschriften an die Verordnung (EU) 2016/679, LT-Drs 21/1163.

⁹⁰ Entwurf eines Gesetzes zur Anpassung des Landesdatenschutzgesetzes und weiterer datenschutzrechtlicher Vorschriften im Zuständigkeitsbereich des Ministeriums für Inneres und Europa Mecklenburg-Vorpommern an die Verordnung (EU) 2016/679 und zur Umsetzung der Richtlinie (EU) 2016/680.

⁹¹ Bremisches Ausführungsgesetz zur EU-Datenschutz-Grundverordnung
(BremDSGVOAG) .

⁹² Gesetzentwurf der Fraktionen der CDU und BÜNDNIS 90/DIE GRÜNEN für ein Hessisches Gesetz zur Anpassung des Hessischen Datenschutzrechts an die Verordnung (EU) Nr. 2016/679 und zur Umsetzung der Richtlinie (EU) Nr. 2016/680 und zur Informationsfreiheit.

⁹³ section 4d (1) FDPA; see also I.A.

⁹⁴ section 4d (1), (5) FDPA; see also I.A.

Länder a consultation obligation according to Art. 36 GDPR may apply. In some of the former data protection acts approvals of higher state authorities were required for the application of research exceptions. Such approval requirements are not existent in the current drafts of the general data protection acts of the Länder (IV.A.).

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

The data subjects rights are now entailed in the GDPR. It is now clear that in the case of further processing the data subject must be informed of the new purpose (Art. 14 (4) GDPR). The German legislator enacted some restrictions to the data subjects rights as Art. 89 (2) GDPR permits it.

In the new FDPA, for example, in section 27 (2), which applies to all types of personal data⁹⁵, it is stated that the rights of data subjects provided in Articles 15, 16, 18 and 21 GDPR shall be limited to the extent that these rights are likely to render impossible or seriously impair the achievement of the research or statistical purposes, and such limits are necessary for the fulfilment of the research or statistical purposes. Further, the right of access according to Article 15 of Regulation (EU) 2016/679 shall not apply if the data are necessary for purposes of scientific research and the provision of information would involve disproportionate effort. Disproportionate effort shall be affirmed if particularly large volumes of data are processed for the research.⁹⁶

In Lower Saxony section 13 (5) of the new Data Protection Act of Lower Saxony it is provided that the rights of data subjects provided in Articles 15, 16, 18 und 21 GDPR shall not be granted if it is likely that using such rights would render impossible or seriously impair the achievement of the scientific or historical research purpose and the exclusion of these rights are necessary to achieve those purposes.

In the other Länder the provisions are very similar to the provision in the draft for Lower Saxony, only in Bremen and Hessen it is additionally provided that - likewise as regulated in section 27 (2) FDPA - the right of access according to Article 15 of Regulation (EU) 2016/679 shall not apply if the data are necessary for purposes of scientific research and the provision of information would involve disproportionate effort.

5. Further processing for research purposes under the GDPR

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

⁹⁵ Buchner, B. and Tinnefeld, M.-T., in in: DS-GVO, BDSG Kommentar (edt. Kühling, J. and Buchner, B.), 2. edt., 2018, section 27 margin number 19.

⁹⁶ Buchner, B. and Tinnefeld, M.-T., in in: DS-GVO, BDSG Kommentar (edt. Kühling, J. and Buchner, B.), 2. edt., 2018, section 27 margin number 19; [BT-Drs. \(German Parliament Document\) 18/11325](#), p. 99-100.



Partners

The rules set out by the GDPR with regard to further processing will be directly applicable. In the context of scientific research Art. 5 (1)(b) GDPR and Art. 89 (1) GDPR are of major relevance. Art. 5 (1)(b) GDPR declares that “further processing for archiving purposes in the public interest, scientific or historical research purposes or statistical purposes shall, in accordance with Article 89 (1), not be considered to be incompatible with the initial purposes.” Art. 89 (1) GDPR states that: “Processing for archiving purposes in the public interest, scientific or historical research purposes or statistical purposes, shall be subject to appropriate safeguards, in accordance with this Regulation, for the rights and freedoms of the data subject.”

From this follows that the European legislator - while upholding a high protection level for data subjects - wanted to privilege processing of personal data for research purposes when it comes to compliance with the principle of purpose limitation. The relation to the principle of lawfulness - which requires that the processing of personal data is based on the informed consent of the data subject or a legal ground⁹⁷ - is, however, unclear. In that context recital 50 GDPR must be considered which stipulates that: „The processing of personal data for purposes other than those for which the personal data were initially collected should be allowed only where the processing is compatible with the purposes for which the personal data were initially collected. In such a case, no legal basis separate from that which allowed the collection of the personal data is required.” Recital 50 GDPR also states: “Further processing for archiving purposes in the public interest, scientific or historical research purposes or statistical purposes should be considered to be compatible lawful processing operations.” The impact and meaning of Recital 50 GDPR is intensively discussed among German legal scholars. The core question arising is whether the legal basis of the original collection can serve as basis for the further processing although the actual conditions stipulated by that (original) legal ground are not fulfilled, e.g. if the collection and processing of the data was originally based on the informed consent of the data subject, but that consent does not cover the new purpose, can the further processing still be based on that initial consent given by the data subject?

Some of the legal scholars affirm this if the new purpose is compatible with the initial purpose and refer to Art. 5 (1)(b) GDPR which declares that the further processing shall not be considered incompatible and the wording of recital 50 GDPR.⁹⁸ Hence, the legal ground functioning as a legal basis for the first processing covers also any further processing of the personal data if the new purpose is a compatible one. Consequently, if the new purpose is scientific research and the conditions of Art. 89 (1) GDPR are met, the processing will be lawful.

⁹⁷ Art. 5 (1) (a), 6 and 9 GDPR; Art. 6 (1) GDPR: “Processing shall be lawful only if and to the extent that at least one of the following applies: [...]”; Art. 9 GDPR: “ 1. Processing of personal data revealing racial or ethnic origin, political opinions, religious or philosophical beliefs, or trade union membership, and the processing of genetic data, biometric data for the purpose of uniquely identifying a natural person, data concerning health or data concerning a natural person's sex life or sexual orientation shall be prohibited. 2. Paragraph 1 shall not apply if one of the following applies: [...]”:

⁹⁸ Frenzel, E. M., in: Paal, B. and Pauly, D. (edt.), *Datenschutz-Grundverordnung*, 2017, Art. 5 margin number 3; Richter, P., *Big Data, Statistik und die Datenschutz-Grundverordnung*, DuD 2016, p. 584; Piltz, K., *Die Datenschutz-Grundverordnung*, K & R 2016, p. 566; Schulz, S., in: Gola, P. (edt.), *Datenschutz-Grundverordnung VO (EU) 2016/679*, 2017, p. 256; Kühling, M., and Martini, M. in *Die Datenschutz-Grundverordnung: Revolution oder Evolution im europäischen und deutschen Datenschutzrecht*, EuZW 2016, p. 451; Härting, N., *Datenschutz-Grundverordnung*, 2016, p. 124.

Other scholars argue that Recital 50 must be interpreted narrowly or must be neglected at all.⁹⁹ They state that especially when it comes to further processing for privileged purposes such as scientific research purposes or statistical purposes, the interests of the data subject would despite the reference to Art. 89 (1) GDPR not be sufficiently protected.¹⁰⁰ Accordingly, the processing of personal data must have an own legal ground; a fictional extension as suggested by the opposing opinion is not sufficient to comply with the principle of lawfulness as laid down in Art. 5 (1) (a) GDPR. It is particularly argued that according to Art. 8 (2) of the Charter of Fundamental Rights of the European Union, personal data must be processed on the basis of the consent of the data subject or another legitimate basis in the law.¹⁰¹ Recital 50 itself, however, cannot be regarded as a legal ground although it is part of the Regulation¹⁰² and it is consistent practice to use recitals for interpretation of the legal text. However, recitals are not binding. The European Court of Justice has stated in its jurisdiction that “it should be borne in mind that the preamble to a Community act has no binding legal force and cannot be relied on either as a ground for derogating from the actual provisions of the act in question or for interpreting those provisions in a manner clearly contrary to their wording”.¹⁰³ However, one could also argue, that Recital 50 indeed is not to be seen as a legal basis, but underlines, what Art. 5 1 (b) GDPR stipulates: scientific research is compatible with the original purpose of the processing and therefore there is no need for a new basis. Any other interpretation would lead to the question, what Art. 5 I (b) GDPR was meant to serve for.

All in all, the question arises why the European legislator has not stated explicitly in the legal text (i.e. in the articles) that the further processing can be based on the legal ground for the collection of the personal data. Fact is that the principle of lawfulness has been a very established principle and a modification could have been implemented by an undoubtedly clear provision in the binding part of the Regulation.

However, in most cases the difference might be not that decisive as all the provisions relating to the measures to protect the data subject are also required by Art. 89 (1) GDPR and would have to be complied with anyways. It is only the weighing of interests that, for example, section 27 (1) of the new FDPA requires that would fall away. As long as the research promises considerable improvements for health care and social security the public interest in pursuing the research will prevail.

⁹⁹ Heberlein, H., in: Ehmann, E. and Selmayr, M. (edt.), *Datenschutz-Grundverordnung*, p. 267; Schantz, P., *Die Datenschutz-Grundverordnung – Beginn einer neuen Zeitrechnung im Datenschutzrecht*, NJW 2016, p. 1844; Schantz, P., in: Wolff, A. and Brink, S., (edt.), *Beck Online Kommentar Datenschutzrecht*, Art. 5, margin number 22; Herbst, T., in: Kühling, J. and Buchner, B. (edt.), *Datenschutz-Grundverordnung: DS-GVO*, 2017, pp. 205-206.

¹⁰⁰ Schantz, P., in: Wolff, A. and Brink, S., (edt.), *Beck Online Kommentar Datenschutzrecht*, Art. 5, margin number 22.

¹⁰¹ Schantz, P., *Die Datenschutz-Grundverordnung – Beginn einer neuen Zeitrechnung im Datenschutzrecht*, NJW 2016, p. 1844; Heberlein, H., in: Ehmann, E. and Selmayr, M. (edt.), *Datenschutz-Grundverordnung*, p. 267.

¹⁰² Herbst, T., in: Kühling, J. and Buchner, B. (edt.), *Datenschutz-Grundverordnung: DS-GVO*, 2017, p. 205.

¹⁰³ ECJ, C-345/13.

6. Health data sources for research purposes

a. Sources of data and their regulation

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

The current legal framework does not provide specific provisions for anonymized or pseudonymized health data. In case data is anonymized in a legal sense, the data protection regulations do not apply any more. However, as mentioned above usually the law requires that data must be anonymized as soon as the research purpose allows it. If the research purpose requires the identification of the data subjects, data must be pseudonymized. In that respect some of the laws may be more specific and require, for example, a data custodian.

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.

Under the current legal framework health data can be collected from patients either on the basis of the informed consent or other legal grounds may provide a legal basis, e.g. research exemptions that have been introduced under I.B., e.g. section 28 (6) No 4 of the old FDPA. Preferably, in the area of research, patients should be asked for their informed consent.

Section 4a of the old FDPA stipulates certain conditions for a valid informed consent. Accordingly, consent must be given freely. The data subject shall also be informed of the purpose of the processing. It has been under debate how specific a consent must be and whether broad(er) forms of consent constitute valid forms of consent.¹⁰⁴ Data subjects should be also told about the consequences of withholding consent. For special categories of data it is stated in section 4a (3) of the former FDPA that the consent must refer expressively to such data.

There are also certain formal requirements that need to be considered. Consent shall be given in writing unless the circumstances require any other form. Whether an electronic consent - without using an electronic signature - is sufficient as a legal basis has been unclear. Section 4a (2) of the old FDPA entails a specific regulation for research but allows another form only under very limited circumstances.¹⁰⁵ Generally, the writing requirement should protect

¹⁰⁴ Pommerening, K. et. al., Leitfaden zum Datenschutz in medizinischen Forschungsprojekten, 2014, p. 38-42; Kondylakis et. al., Donor's support tool: enabling informed secondary use of patient's biomaterial and personal data, International Journal of Medical Informatics 2017, p. 284.

¹⁰⁵ Section 4a (2) FDPA: "In the field of scientific research, a special circumstance pursuant to sub-section 1 third sentence above shall also be deemed to exist where the defined purpose of research would be impaired

the data subject and make him or her aware of the importance of the decision, so that it could be also opined that only under very limited circumstances an exception from the writing requirement can be made. Section 4a (1) of the old FDPA also states that if consent is given with other written declarations it must appear in a distinguishable form.

In general, the described requirements also are requirements of other data protection acts, e.g. the data protection acts of the Länder. For some of the special acts there will be additional requirements for a valid informed consent, e.g. for clinical trials the consent must be in writing¹⁰⁶ and according to the Genetic Diagnostic Act a special genetic counselling must be provided¹⁰⁷.

The hospital acts in the various Länder may also provide specific provisions when treatment data may be used by doctors and medical staff for research purposes.¹⁰⁸ The example of the Hospital Act of Hamburg is provided in I.B.

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

With regard to collecting data for research on basis of the informed consent principally Art. 9 (1)(a) and 7 GDPR will determine the legal conditions for a valid consent. Most of the conditions now entailed in the GDPR have been also entailed in the former German national data protection acts, e.g. the above introduced section 4a of the former FDPA. The GDPR, however, brings some clarification to the issue whether broader forms of consent are permissible as it provides in Recital 33 reference points for the acceptance of such broader forms of consent. Accordingly, data subjects should be allowed to give their consent to certain areas of scientific research if the recognised ethical standards for scientific research are followed. However, it is also stated that data subjects should have the opportunity to give their consent only to certain areas of research or parts of research projects to the extent allowed by the intended purpose.

Under the GDPR electronic consent can be legally securely used as the legal text of the Regulation does not require a written informed consent and Recital 32 even explicitly states that consent can also be declared by electronic means. However, special laws, such as the Medicinal Products Act or in the future the Clinical Trials Regulation, may require that consent should be in writing.¹⁰⁹

Eventually, if consent cannot be obtained, the data can be collected on another legal basis, such as section 27 of the new FDPA, which has been introduced in IV.A, unless it is explicitly foreseen that the data can only be obtained with

considerably if consent were obtained in writing. In such case the information pursuant to sub-section 1 second sentence above and the reasons from which considerable impairment of the defined purpose of research would arise shall be recorded in writing.”

¹⁰⁶ Section 40 (1) and (2a) Medicinal Products Act.

¹⁰⁷ Section 9 and 10 Genetic Diagnostics Act.

¹⁰⁸ A good overview is presented in Schneider, U. K., Sekundärnutzung klinische Daten - rechtliche Rahmenbedingungen, 2015, p. 87-89.

¹⁰⁹ Art. 29 and Recital 30 Regulation (EU) No 536/2014 of the European Parliament and of the Council of 16 April 2014 on clinical trials on medicinal products for human use and repealing Directive 2001/20 /EC.

the informed consent of the person, e.g. in the context of clinical trials¹¹⁰ or when the Genetic Diagnostic Act¹¹¹ applies.

- **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.

The researcher who wants to obtain data from medical staff and hospitals underlies the usual restrictions set up by the data protection acts. This means a legal basis for the collection and subsequent processing is required. Special provisions may apply to the medical staff that provide the data to the researcher. For example, the hospital acts contain specific provisions how data can be shared in-house in the hospital and with external parties. According to section 12 of the Hospital Act of Hamburg, physicians are allowed to process patient data for their own research if they do not infringe legitimate interests of the patients. Patient data may also be transferred for specific research projects to third parties outside of the hospital if either the data cannot be attributed to a specific person or if the attribution to a specific person is required by the research purpose and the patient gave his consent to the transfer. If attribution to a specific person is required by the research purpose and the consent cannot be obtained with reasonable means the transfer would still be allowed if this is necessary for the purposes of the specific scientific research project and if the public interest in carrying out the research project substantially outweighs the legitimate data subject's interest. In the latter two cases the personal data have to undergo pseudonymisation and the identifying data must be stored separately (II.B.).

Additionally, medical staff as data providers also need to consider their secrecy obligations (II.C.(i)).

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 answer to this question depends on the opinion adopted with regard to further processing. If the further processing can also be based on the provision that covered the collection of the data this would simplify proceedings. In case the stricter view is adopted the legal reforms do not substantially modify the conditions of access to data gathered by health professionals and health care establishments for research purposes (as things stand at present).

- **PRIVATE DATABASES**

¹¹⁰ I.A.

¹¹¹ I.A.

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.

The establishment of private databases with health data for research purposes needs to be in compliance with the applicable data protection law. Which law has to be considered depends, as has been explained in I.A., on the individual circumstances.

In general, it can be said that the storage of health data for research purposes that have been only broadly determined during the collection, e.g. for general research purposes, or will be determined only in the future have been causing issues because the research exemptions require that the data will be used for a specific research purpose. Only in limited cases, e.g. the cancer register acts or section 12a of the Hospital Act of Hamburg, the retention of data for general research purposes is permitted explicitly. Section 12a of the Hospital Act of Hamburg also provides that the establishment of a database for general research purposes must be notified to the supervisory authority. For private bodies - in case the FDPA applies¹¹² - possibly registration obligations according to section 4d (1) of the old FDPA apply.

In case the data was collected with the consent of the data subject, the use of broad forms of consent has been under criticism (IV.A.).

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

In how far data retention for longer periods and broad or general research purposes is covered by section 27 of the new FDPA will have to be discussed, the wording of the provision is not unambiguous and leaves room for interpretation.

Although Art. 5 (1)(b) GDPR upholds that data must be collected for specific purposes, the use of broader forms of consent, e.g. research for specific types of diseases or branches of diseases is more or less acknowledged even today¹¹³ and the Regulation indicates at least in relation to the consent of data subjects that broader purposes in the area of medical research are necessary and acceptable.¹¹⁴

- **PUBLIC DATABASES**

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

¹¹² Special acts may supersede the general provisions of the FDPA (I.A.).

¹¹³ Pommerening, K., op. cit., p.39.

¹¹⁴ Recital 33 GDPR.

- Cancer Registries

Firstly, in Germany, there are cancer registries, which, due to the federal system, are to be found on the Länder level. There are two different types of cancer registries: clinical cancer registries, aimed at quality assurance regarding medical care and treatment, and epidemiologic cancer registries, which deal with population-based analysis of the occurrence of cancer.¹¹⁵

Under certain circumstances, the data of the epidemiologic registers may be used by external scientists for their research projects; with regard to clinical registers, such a use is planned for the future.¹¹⁶

Epidemiologic Cancer Registries

Since 2009, an epidemiologic cancer registration takes place in all the Länder of Germany.¹¹⁷

For example, in Lower Saxony, the Epidemiologic Cancer Registry (Epidemiologisches Krebsregister Niedersachsen - EKN) is an institution of the Land Lower Saxony and is subject to the functional supervision of the Ministry of Social Affairs, Health and Equality.¹¹⁸ The epidemiologic cancer registry is regulated by the Act on the epidemiologic cancer registry of Lower Saxony (Gesetz über das Epidemiologische Krebsregister Niedersachsen - GEKN).¹¹⁹ According to its section 1, the purpose of this registry is, among others, to provide data for epidemiological research and for scientific research.

The registry publishes an annual report of its own statistical-epidemiological analysis of the cases registered in Lower Saxony, presenting the development and regional differences, which is freely available online (section 14 GEKN).¹²⁰ Additionally, statistical data concerning incidence and mortality can be accessed freely via an online database.¹²¹ If information beyond the publicly available data is needed for a purpose within the tasks of the registry, data may be made available under certain circumstances, laid down in section 11 GEKN.

Anonymised data can be transferred on request and in accordance with section 11 (1) GEKN, which prohibits the data receiver to merge the data with other data so that a data subject can be identified. Higher requirements are

¹¹⁵ See Robert Koch Institute,
https://www.krebsdaten.de/Krebs/DE/Content/ZfKD/Archiv/unterschiede_epi_klin_reg.html.

¹¹⁶ https://www.krebsdaten.de/Krebs/DE/Content/ZfKD/Archiv/unterschiede_epi_klin_reg.html.

¹¹⁷ Robert Koch Institute, Bericht zum Krebsgeschehen in Deutschland 2016, p. 17,
https://www.krebsdaten.de/Krebs/DE/Content/Publikationen/Krebsgeschehen/Krebsgeschehen_download.pdf?_blob=publicationFile.

¹¹⁸ <http://www.krebsregister-niedersachsen.de/>.

¹¹⁹ http://www.nds-voris.de/jportal/portal/t/g12/page/bsvorisprod.psm?pid=Dokumentanzeige&showdoccase=1&js_peid=Trefferliste&documentnumber=5&numberofresults=14&fromdoctodoc=yes&doc.id=jlr-KrebsRegGND2013rahmen&doc.part=X&doc.price=0.0&doc.hl=1#jlr-KrebsRegGND2013pP1.

¹²⁰ Accessible (in German) via: <http://www.krebsregister-niedersachsen.de/index.php/aktueller-jahresbericht>.

¹²¹ <http://www.krebsregister-niedersachsen.de/index.php/datenbankabfrage>.

put on the transfer of personal data; they are laid down in section 11 (2)-(4) GEKN. Regarding personal data, they can be transferred upon request only if needed for a project that is important and for the public benefit, which cannot, or only with a disproportionate effort, be realised in another way, and if the line ministry approves of the transfer. Furthermore, the purpose and the measures foreseen for the protection of the data need to be elaborated in the request. If the data, in derogation from the indications in the request, shall be used for another purpose or if the measures for the protection of the data shall be changed, this is only permitted if the subdepartment of the registry gives permission to this and the line ministry approves of it. If data shall be transferred that permit the identification of a data subject, written consent of this person is required (section 11 (3) GEKN). There are very few exceptions to this requirement, which can be found in section 11 (4) GEKN: e.g., for transfers confined to the patient ID number, the date of death and the cause of death of deceased persons, such consent is not necessary.

As stipulated in section 1 (1) Bundeskrebsregisterdatengesetz - BKRG¹²², there is a federal centre for cancer registry data (Zentrum für Krebsregisterdaten - ZfKD), which is maintained by the Robert Koch Institute (Robert-Koch-Institut - RKI). The federal centre for cancer registry data brings together the epidemiological cancer-related data communicated by each of the Länder epidemiologic cancer registries to analyse them and to create a dataset covering all the data from the Länder registries (see sections 2, 3 BKRG). In section 5 (1) and (2) BKRG it is laid down that this dataset is used for the fulfilment of the tasks of the federal centre for cancer registry, and that the Länder cancer registries may use the dataset upon request. On top of that, third parties may make an application for the use of the dataset according to section 5 (3) BKRG. This provision implies that the use may be granted if the third party substantiates a legitimate interest, in particular of scientific kind. The third party's application shall be supported with reasons, especially regarding the purpose and extent of the usage, and will be submitted to the federal centre's advisory board, which will be asked to give an opinion on the matter. On top of that, the ZfKD estimates the numbers of cancer in Germany on an annual basis (incidence, mortality, prevalence and viability); the statistical results of this estimation are freely accessible online.¹²³

Clinical Cancer Registries

In principle, each Land is supposed to establish and maintain a cancer registry, covering its territory (see section 65c (1) first sentence Social Act No 5). However, the establishment of these registries in all the Länder is still ongoing.

In Lower Saxony, the clinical cancer registry of Lower Saxony (Klinisches Krebsregister Niedersachsen - KKN) has been established in December 2017. The details of this registry are laid down in the act on the clinical cancer registry of Lower Saxony (Gesetz über das Klinische Krebsregister Niedersachsen - GKKN).¹²⁴ In the GKKN, there is no provision dealing with the access to the data for research purposes to be found. This complies with the purpose of the clinical cancer registry as explained above.

. Biobanks

¹²² <http://www.gesetze-im-internet.de/bkrg/BJNR270700009.html>.

¹²³ In English via: https://www.krebsdaten.de/Krebs/EN/Database/databasequery_step1_node.html, and in German via: https://www.krebsdaten.de/Krebs/DE/Datenbankabfrage/datenbankabfrage_stufe1_node.html.

¹²⁴ <http://www.nds-voris.de/jportal/portal/t/du3/page/bsvorisprod.psml?doc.hl=1&doc.id=jlr-KIKrebsRegGNDrahmen&documentnumber=1&numberofresults=51&doctyp=Norm&showdoccase=1&doc.part=X¶mfromHL=true#jlr-KIKrebsRegGNDp1>.



Partners

Another case in which public authorities make available health data are biobanks. In biobanks, human biological samples are collected and are supplemented by personal and disease-related patient data, so that they constitute a union of biomaterial and data collection.¹²⁵ There are a number of biobanks to be found in Germany. The German Biobank Registry¹²⁶ lists 128 biobanks and provides contact information on the registered biobanks. Many biobanks are institutions of public bodies, in particular as they are mainly established at medical schools, e.g. the Central Biobank of the faculty of medicine of the university of Münster¹²⁷, the biobank “Rhinevit” of the university hospital of Düsseldorf¹²⁸, the NCT-Gewebebank of the university hospital of Heidelberg¹²⁹, the “CCC ER-EMN Gewebebank” of the university hospital of Erlangen¹³⁰, the “Interdisciplinary Center for Biobanking-Lübeck” (“ICB-L”) of the university of Lübeck and the university hospital of Lübeck¹³¹, or the “Hannover Unified Biobank (HUB)” of the Hannover Medical School¹³². Therefore, in principle, the data protection rules of the Land in which they are located are applicable to these biobanks when processing and making available data. If a corporate body under public law or its organisationally independent institution is a competitor and processes the data in fulfilment of the competitive task, the provisions of the FDPA for private bodies are applicable.¹³³ Many biobanks fulfil these criteria, so that in many cases the rules of the FDPA apply.¹³⁴ However, not all the biobanks provide access for research purposes: Some of them only provide biomaterial for diagnostic and therapeutic purposes.¹³⁵ In case public hospitals have their own biobank the special provisions stipulated in hospital acts (e.g. section 12a Hospital Act of Hamburg) must be considered.

Although the use of data in biobanks raises particular questions concerning the achievement of balance between conflicting fundamental rights, there are no specific provisions addressing the structural characteristics of biobanks, e.g. with regard to purpose limitation,¹³⁶ so that the general data protection regime as explained above applies with the exception of section 12a Hospital Act of Hamburg. Furthermore, for the legal admissibility of the transfer and

¹²⁵ Pommerening, K. et al., Leitfaden zum Datenschutz in medizinischen Forschungsprojekten, 2014, p. 205.

¹²⁶ <http://www.biobanken.de/en-gb/home.aspx>.

¹²⁷ <https://www.medizin.uni-muenster.de/zbbmf/>.

¹²⁸ <http://www.uniklinik-duesseldorf.de/unternehmen/kliniken/poliklinik-und-funktionsbereich-fuer-rheumatologie/hiller-forschungszentrum/core-facilities/>.

¹²⁹ <https://www.klinikum.uni-heidelberg.de/NCT-Gewebebank.6979.0.html>.

¹³⁰ <http://www.ccc.uk-erlangen.de/forschung/zentrale-einrichtungen/ccc-gewebebank/>.

¹³¹ <https://www.uni-luebeck.de/en/biobank.html>.

¹³² <https://www.mh-hannover.de/biobank.html>.

¹³³ According to an exception to the exception, to be found in Länder data protection acts, e.g. section 2 (3) NDSG in Lower Saxony.

¹³⁴ See Cornelius, K., Die Bereitstellung humaner Alt-Bioproben durch eine Biobank, MedR 2017, p. 16.

¹³⁵ Statement of the German Ethics Council on Human Biobanks for Research (Deutscher Ethikrat, Humanbiobanken für die Forschung. Stellungnahme), 2010, p. 7, accessible via: <http://www.ethikrat.org/dateien/pdf/stellungnahme-humanbiobanken-fuer-die-forschung.pdf>

¹³⁶ Statement of the German Ethics Council on Human Biobanks for research, 2010, p. 18. <http://www.ethikrat.org/dateien/pdf/stellungnahme-humanbiobanken-fuer-die-forschung.pdf>.

analysis of the data and material, inter alia, the conditions for a valid informed consent are relevant (see above VI.A.). For further details regarding the access to data in biobanks see in particular the analysis on the application of the national framework to the EAGLE cases (case 3, Chronic Lymphocytic Leukemia - CLL, see B.3.). In so far as genetic data is concerned, the Genetic Diagnostics Act (GenDG) might have to be taken into account (see above I.A.).

- Information system for health care data (data transparency)

The German Institute of Medical Documentation and Information (Deutsches Institut für Medizinische Dokumentation und Information - DIMDI) is a government agency in the department of the Federal Ministry of Health (i.e. a public body) and maintains the information system for health care data (Informationssystem Versorgungsdaten); as such, it provides health care data stemming from the statutory health insurances in Germany,¹³⁷ carrying out the data transparency tasks as laid down in sections 303a-303e Social Act No 5 (SGB V). According to section 303e (1) SGB V, the data saved in this information system can be used and processed i.a. by universities and other institutions conducting independent research, in so far as the data are serving scientific purposes (the institutions that can use and process the data are called authorized users). The information system gathers data as listed in section 268 (3) 14th sentence in conjunction with first sentence lit. 1-7 SGB V, which are the insurance benefits and days e.g. in the areas hospital, inpatient follow-up rehabilitation, pharmaceuticals, and sick pay. Section 303e (2) Social Act No 5 stipulates the purposes for which the use and processing is particularly permitted, e.g. for long-term longitudinal analysis, analysis of the courses of treatment etc. (lit. 4). Further details are regulated in the Datentransparenzverordnung - DaTraV¹³⁸. The data are made available upon request, and the request needs to indicate the purpose of the use and if the data will be combined with each other or with other datasets (section 5 (2) DaTraV). The request will be considered, assessing e.g. user authorization as regulated in section 303e (1) SGB V, the purpose as listed in section 303e (2) Social Act No 5, the sufficiency and necessity of the extent and structure of the data, and if in case of combination of the data a re-identification is possible (section 5 (3) DaTraV). Usually, data that are transferred are anonymised, only exceptionally can they be pseudonymised (section 5 (4) and (5) DaTraV).

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

As matters stand at the moment, under the revised legal framework the conditions for the use of health data made available for research purposes by public bodies do not specifically change. For changes see the elaborations on the general legal conditions under the revised framework.

¹³⁷ <https://www.dimdi.de/static/en/versorgungsdaten/index.htm>.

¹³⁸ <http://www.gesetze-im-internet.de/datrav/BJNR189500012.html>.

b. Application of the national framework to the AEGLE cases

In the AEGLE project, the “research objective is to establish the use of Big data analysis in the prediction of outcomes in three working scenarios: Chronic Lymphocytic 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”. [112]

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.

It will be assumed for the analysis of the following use cases that the data used by the researcher are not to be regarded as de-facto anonymous data.¹³⁹

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.

Legal situation under the Data Protection Directive

In general, the informed consent of the patient is a sufficient legal basis for processing his or her personal data for research purposes. As mentioned in VI.A., the use of broad forms of consent (consent for general research purposes) has been called into question, but forms of consent that relate to a certain disease or at least to branches of diseases and which give specific conditions about who has access to the data and under which circumstances data will be shared with third parties were more or less seen as acceptable. As a rule of thumb, the more specific the consent is, the more likely it is that the processing is in compliance with German data protection law. In case the consent was given specifically for AEGLE and the other conditions for a valid informed consent (VI.A.) have been complied with, the consent functions as a legal basis for the processing of the personal data in the AEGLE project. In case the former consent does not cover the research pursued in the AEGLE project, new consent must be sought or a research exemption must cover the further processing of the personal data within the AEGLE project.

¹³⁹ If the researcher does not have access to the pseudonymization key and if it is practically impossible that the data will be de-identified by the researcher and kept in a secure environment it is partly opined that the data can be regarded as anonymous in a legal sense. However, other authors have denied the concept of “relative anonymity” (Pommerening, K. et. al., op. cit., p. 42-44.).

The data must be appropriately protected, e.g. by efficient pseudonymisation procedures if the research purpose does not permit to anonymize the data.¹⁴⁰ Other appropriate technical and organisational measures to protect the data should be implemented as well.

Professional secrecy obligations need to be complied with as well. Physicians who give access to data of their patients to researchers should efficiently pseudonymise the data and properly inform the patients about the envisaged research as well as the measures that will be taken to protect the patient in his right to data protection (II.C.(i)).

Physicians undertaking the research will have to seek advice from an ethics committee, e.g. section 15 Berufsordnung der Ärztekammer Niedersachsen (I.A.). The professional rules of the other Länder foresee similar provisions, e.g. section 15 [Berufsordnung der Ärztekammer Berlin](#).

Possibly, researchers from universities may be able to consult an ethics committee apart from the obligations in the professional laws. Universities in Lower Saxony, for instance, have established ethics committees according to the [transparency guidelines issued by the university conference of Lower Saxony](#) (Landeshochschulkonferenz Niedersachsen) and the Ministry of Science and Culture of Lower Saxony. The consultation seems not to be mandatory but is recommended as it gives researchers the possibility to get ethical feedback.

Possibly, in case private bodies are pursuing the research, a registration obligation according to section 4d (1) of the old FDPA applies (I.C.).

Principally, in case the patients have been informed about the use of the data for AEGLE specifically, no additional information obligation arises.

Legal situation under the GDPR

The legal situation will change insofar as broader forms of consent are more likely to be accepted (VI.A.). If the initial consent covers also the processing of the treatment data for AEGLE, the processing will not pose any problems with regard to the purpose limitation principle and the principle of lawfulness.

However, in case the informed consent does not cover the research in the AEGLE project, the subsequent processing would constitute a change in the purpose, which would, according to Art. 5 (1)(b) GDPR, be in line with the purpose limitation principle as scientific research is a compatible purpose.

With good arguments it therefore can be assumed, that no further legal basis is needed. However, it remains to be seen if this interpretation prevails. Hence, to be on the safe side, one should clarify whether a legal basis covers the processing of the data for the envisaged research or not (V.). Under IV.A. examples of relevant provisions have been introduced. In any case the provisions that implement Art. 89 (1) GDPR must be complied with.¹⁴¹

Researchers will have to undergo a data protection impact assessment according to Art. 35 GDPR (I.C. and IV.B.).

¹⁴⁰ Section 40 (2) of the old FDPA (II.C.) or 25 of the old Data Protection Act of Lower Saxony; section 9 of the old FDPA or section 7 of the old Data Protection Act of Lower Saxony.

¹⁴¹ Assuming section 27 of the new FDPA applies this would be section 27 (1) second sentence as well as section 27 (3).

Physicians undertaking the research will have to seek advice from an ethics committee, e.g. section 15 Berufsordnung der Ärztekammer Niedersachsen (I.A.). The professional rules of the other Länder foresee similar provisions, e.g. section 15 [Berufsordnung der Ärztekammer Berlin](#).

Generally, the information obligations in the GDPR have been extended. Nevertheless, in case the patients have been informed about the use of the data for AEGLE specifically, no additional information obligation arises. If, otherwise, the consent is not valid because it is not determined enough, the data subject must be informed about the new research project. An exemption to such notification obligation may apply according to Art. 14 (5)(b) GDPR.

Possibly, researchers from universities may be able to consult an ethics committee apart from the obligations in the professional laws. Universities in Lower Saxony, for instance, have established ethics committees according to the [transparency guidelines issued by the university conference of Lower Saxony](#) (Landeshochschulkonferenz Niedersachsen) and the Ministry of Science and Culture of Lower Saxony. The consultation seems not to be mandatory but is recommended as it gives researchers the possibility to get ethical feedback.

2. Intensive Care Unit (ICU)

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

Legal situation under the Data Protection Directive

The original collection and subsequent processing was conducted for treatment purposes. Using the data for the AEGLE project for research qualifies as a change in the purpose.

As the further processing cannot be based on (new) consent it must be checked if a research exemption applies, e.g. section 28 (8) of the former FDPA, section 12 of the Hospital Act of Hamburg, which among other things allows In-House Research with treatment data (II.B.), or section 25 of the Data protection Act of Lower Saxony (II.B.). Which regulation must be considered depends on the scope of application (I.A., II.A.). For private bodies section 28 (8) of the former FDPA is relevant.

The research exemptions often require that the public interest in the research substantially outweighs the interest of the data subject in not using the data for the research. As the project is aiming for improving health care in intensive care units, this requirement should be fulfilled. Additionally, data must be anonymized or if the research purpose requires to work with personal data, properly pseudonymized. Other appropriate technical and organisational measures to protect the data must be implemented as well.

Professional secrecy obligations have to be complied with, too. Physicians who give researchers access to data of their patients should efficiently pseudonymize the data and ideally, but not compulsory if the data has been properly pseudonymized, inform the patients about the envisaged research as well as the measures that will be taken to protect the patient in his right to data protection (II.C.(i)).

Possibly, if a private body is involved, the registration obligation according to section 4d (1) of the old FDPA applies (I.C.).

Physicians who undertake the research will have to seek advice from an ethics committee, e.g. section 15 Berufsordnung der Ärztekammer Niedersachsen (I.A.). The professional rules of the other Länder foresee similar provisions, e.g. section 15 [Berufsordnung der Ärztekammer Berlin](#).

Possibly, researchers from universities may be able to consult an ethics committee apart from the obligations in the professional laws. Universities in Lower Saxony, for instance, have established ethics committees according to the [transparency guidelines issued by the university conference of Lower Saxony](#) (Landeshochschulkonferenz Niedersachsen) and the Ministry of Science and Culture of Lower Saxony. The consultation seems not to be mandatory but is recommended as it gives researchers the possibility to get ethical feedback.

Principally, in the case of change of the purpose and the further processing is pursued by the same controller, data subjects do not have to be informed about the use of the data for the research (III.). In case the data controller doing research for AEGLE is a different person than the one who had collected the data for the first time, the data subject must be informed about the collection and new purpose (III.) unless an exemption to such notification obligation applies because the notification would require disproportionate effort (e.g. section 33 (2) FDPA).

Legal situation under the Regulation

The original collection and subsequent processing was for treatment purposes. Using the data for the AEGLE project qualifies as a change in the purpose.

The further processing of the personal data within the AEGLE project would, according to Art. 5 (1)(b) GDPR, constitute a compatible purpose as it concerns scientific research.

With good arguments it therefore can be assumed, that no further legal basis is needed. As has been mentioned in V., it remains to be seen if this interpretation prevails. Hence, to be on the safe side, it should be checked whether the further processing falls under a research exemption or not if the processing cannot be based on the informed consent of the data subject. It must be evaluated what the applicable law would be. In case the new FDPA applies, e.g. if private bodies pursue the research, it should be clarified if the conditions of section 27 are complied with. For that, the processing must be necessary for achieving the research purposes and the interests of the researcher in processing the data must substantially outweigh those of the data subject in not processing the data, which is to be affirmed (see above). The other conditions stipulated in section 27 of the new FDPA (IV.A.) would have to be followed as well, e.g. the data must be anonymized as soon as the research purpose allows it. If the relation to the data subject is required from the research purpose, data must be efficiently pseudonymized.

In any case the provisions that implement Art. 89 (1) GDPR must be followed: Assuming section 27 of the new FDPA applies, this would be section 27 (1) second sentence, as well as section 27 (3).

Professional secrecy obligations have to be complied with, too. Physicians who give researchers access to data of their patients should efficiently pseudonymize the data and ideally, but not compulsory if the data has been properly pseudonymized, inform the patients about the envisaged research as well as the measures that will be taken to protect the patient in his right to data protection (II.C.(i)).

Physicians undertaking the research will have to seek advice from an ethics committee, e.g. section 15 Berufsordnung der Ärztekammer Niedersachsen (I.A.). The professional rules of the other Länder foresee similar provisions, e.g. section 15 [Berufsordnung der Ärztekammer Berlin](#).



Partners

Possibly, researchers from universities may be able to consult an ethics committee apart from the obligations in the professional laws. Universities in Lower Saxony, for instance, have established ethics committees according to the [transparency guidelines issued by the university conference of Lower Saxony](#) (Landeshochschulkonferenz Niedersachsen) and the Ministry of Science and Culture of Lower Saxony. The consultation seems not to be mandatory but is recommended as it gives researchers the possibility to get ethical feedback.

Researchers will have to undergo a data protection impact assessment according to Art. 35 GDPR (I.C. and IV.B.).

Principally, data subjects must be informed in the case of change of the purpose (IV.B.) also if the further processing for the new purpose (research) is done by the same data controller. An exemption to such notification obligation may apply according to Art. 14 (5)(b) GDPR.

3. Chronic Lymphocytic Leukemia (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.

Legal situation under the Data Protection Directive

As has been mentioned in VI.A and VI.B.1., general forms of consent have been called into question; if the consent has been given for a specific disease or for a branch of diseases, chances are higher that the informed consent constitutes a valid basis for the processing of the data for AEGLE.

However, it seems to make sense to check if the processing could be based on another legal basis, e.g. one of the research exemptions (see a. o. II.B. and VI.A.2.). If the conditions set by the legal ground are fulfilled, the processing would be in compliance with the applicable conditions in terms of data protection. Otherwise new consent must be sought.

In case the data stored in the biobank falls under professional secrecy obligations these have to be complied with, too, which requires efficient pseudonymization of the data (II.C.(i)).

Possibly, a registration obligation according to section 4d (1) of the old FDPA applies (I.C.).

Physicians who undertake the research will have to seek advice from an ethics committee, e.g. section 15 Berufsordnung der Ärztekammer Niedersachsen (I.A.). The professional rules of the other Länder foresee similar provisions, e.g. section 15 [Berufsordnung der Ärztekammer Berlin](#).

Possibly, researchers from universities may be able to consult an ethics committee apart from the obligations in the professional laws. Universities in Lower Saxony, for instance, have established ethics committees according to the [transparency guidelines issued by the university conference of Lower Saxony](#) (Landeshochschulkonferenz Niedersachsen) and the Ministry of Science and Culture of Lower Saxony. The consultation seems not to be mandatory but is recommended as it gives researchers the possibility to get ethical feedback.

In case the consent foresees such an information, researchers will have to inform the data subjects. Also, if the biobank and the data controller conducting research for AEGLE are different legal persons, the data subject must be informed about the collection and new purpose (III.) unless an exemption to such notification obligation applies because the notification would require disproportionate effort (e.g. section 33 (2) FDPA).

The legal situation under the Regulation

In recital 33, the Regulation gives reference points for the acceptance of broader forms of consent. Accordingly, data subjects should be allowed to give their consent to certain areas of scientific research if the recognised ethical standards for scientific research are followed (VI.A.). It must be evaluated whether the consent is valid under the Regulation or not.

In case the consent is not to be regarded as valid the use of the data in the AEGLE project constitutes a further processing.

The further processing of the personal data within the AEGLE project would, according to Art. 5 (1) (b) GDPR, constitute a compatible purpose as it concerns scientific research.

With good arguments it therefore can be assumed, that no further legal basis is needed.

As has been mentioned in V., it remains to be seen if this interpretation prevails. Hence, if the processing cannot be based on the informed consent of the data subject, to be on the safe side, it should be checked if the further processing falls under a research exemption. As for that matter it can be referred to the elaborations in VI.B.2 on the legal situation under the Regulation.

Apart from that, the other elaborations in VI.B.2 on the legal situation under the Regulation have to be considered as well.

Principally, data subjects must be informed in the case of a change of the purpose (IV.B.). In case of a general consent the information obligation will depend on the possible approval of the consent. In case it is legally valid no additional information obligation applies. If, otherwise, the consent is not acceptable because it is not determined enough, the data subject must be informed about the new research project. An exemption to such notification obligation may apply according to Art. 14 (5)(b) GDPR.