5 Consent

5.1 Informed Consent

Who can or must conduct an informative talk with the patient in order to guarantee an informed consent? Can this be done by trained personnel (study nurse, receptionist etc.)? Which other conditions must be observed?

General data protection law does not contain any specific requirements for an informative talk.

According to Article 4 no. 11 GDPR Consent of the data subject is defined as:

> *"any freely given, specific, informed and unambiguous indication of the data subject's wishes by which he or she, by a statement or by a clear affirmative action, signifies agreement to the processing of personal data relating to him or her;"*

However, voluntariness presupposes that the essential information of the data subject is available and that the information has been understood. Irrespective of the legal capacity, the ability to give consent must be determined on the basis of whether the person concerned is capable of understanding and is therefore in a position to understand the consequences of an encroachment on his or her right to informational self-determination made possible by the consent.

Where possible, a distinction should be made as to which legally protected right consent refers to. Consents are required by different legal norms, but may contain different declarations which may relate to different legal interests. Consent according to Article 6a) GDPR or Article 9 Section 2a) GDPR is judged according to the standards of Article 7 and 8 GDPR. It accordingly does not explicitly require an informative talk, this is to be judged differently with consents which are supposed to allow an intervention into the physical integrity, e.g. for an invasive examination. If an invasive examination and data processing are required to participate in a study, which both are to be legitimised by consent, there would be two separate declarations of the patient. In some laws, however, these distinctions become blurred. For example, Section 40 (1) Sentence 3 no. 3c) German Medicines Act (AMG) requires that the consent with regard to participation in a clinical trial must also expressly refer to the collection and processing of information on health. In an international context, a uniform English-speaking and quality-assured consent may be preferred. However, since it cannot be assumed that every study participant speaks English, the consent form in English should be available in the respective national language.

Informed consent in the sense of data protection law can already be achieved solely on the basis of written information provided, without an informing person. However, in order to ensure that questions can be answered competently and that the patients ability to give consent can be ensured, it is always recommended that a sufficiently qualified person be available to provide the information. Specific certificates of specialist knowledge are not required.

Depending on the type of research project, however, **sector-specific regulations may result in different requirements**. For example when it comes to clinical trials of a medicinal product, Section 40 para. 2 of the Medicinal Products Act (Arzneimittelgesetz—AMG) states:

> *"The person concerned shall be informed by an investigator who is a physician, or in the case of a dental trial, a dentist, or by a member of the investigating team who is a doctor, or in the case of a dental trial, a dentist about the nature, significance, risks and implications of the clinical trial as well as about his/her right to withdraw from the clinical trial at any time; a generally comprehensible information sheet is to be handed out to him. Furthermore, the person concerned is to be given the opportunity to have a counselling session with an investigator or a member of the investigating team who is a doctor, or in the case of a dental trial, a dentist about the other conditions surrounding the conduct of the clinical trial."*

Since the AMG does not make a clear distinction between consent to data processing and consent to participation in a clinical trial, the safest way would be to also provide the information required under data protection law as a part of the informative talk required under Section 40 para. 2 AMG.

Similar requirements can be found, for example, in Section 20 para. 1 sentence 4 no. 2, papa. 4) no. 4 and Section 21 no. 3 of the Medical Devices Act (Medizinproduktegesetz—MPG).

Is a (supplementary) country-specific consent advisable here?

A country-specific consent would only be advisable if there are country-specific requirements that differ from each other.

Is the TTP obliged to validate the linguistic correctness e.g. of Lithuanian, Polish or Estonian consents?

Does the TTP have to be able to assure the quality of these consents and guarantee their correctness? Only in this case, the TTP may be able to validate/check the consents and handle or correct errors.

The TTP would only be obliged to check the correctness if the TTP would appear for the processing as controller in the sense of the Article 4 no. 7 GDPR and an ineffectiveness of the consent could result from the linguistic incorrectness. The GDPR does not expressly stipulate a duty to validate, but the data controller must ensure the lawfulness of the processing of personal data (Article 5 Section 2 GDPR).

If the TTP acts as a processor, it shall not be obliged to examine the legality of the contract. If the processor has doubts as to the lawfulness of data processing, he should inform the controller accordingly.

If the TTP is part of the legal entity of the controller, it would be part of the controller and thus would have to ensure the lawfulness of the processing of personal data.

According to the GDPR, consent can be given by electronic means. Does this officially allow the sole use of digital signatures? (i.e. no paper-based consensus is obtained, the signature is recorded and stored directly electronically). Are both of the following option of the electronic signature permitted?

Option 1: Capture via tablet PC and only the signature in reproducible form.

Option 2: Capture via SignPad and signature in reproducible form including biometric information. The complete signature data record is stored in the database.

Both options are permissible according to the GDPR. GDPR does not require a written form in the sense of Section 126 German Civil Code (BGB) according to which a handwritten signature would have to be placed below the consent form. Recital 32 GDPR describes some possibilities how consent could be gathered:

> *"(...) This could include ticking a box when visiting an internet website, choosing technical settings for information society services or another statement or conduct which clearly indicates in this context the data subject's acceptance of the proposed processing of his or her personal data."*

According to GDPR an effective consent can already be declared through conclusive acting. Only because of the principle of accountability should an electronic or written consent be obtained.

However, it should be noted that the national legislator could also prohibit the processing of special categories of personal data on the basis of consent (Article 9 Section 2a) GDPR). This means that the member states can also stipulate further requirements. A member state could, for example, allow only written form or an electronic form. If the legislator can completely exclude the instrument of consent, then it can a fortiori allow consent under increased requirements. This applies in particular to genetic data, biometric data and data concerning health, as for these special sub-categories Article 9 Section 4 GDPR provides a specific opening clause:

> *"Member States may maintain or introduce further conditions, including limitations, with regard to the processing of genetic data, biometric data or data concerning health."*

The German legislator did not transpose this into the BDSG. Only in the area-specific data protection law there are occasionally special requirements.

While § 67b para. 2 Tenth Book of the Social Code (SGB X) so far only contains a provision according to which consent to the processing of personal data "should" be given in writing or electronically for verification purposes in accordance with Art. 7 GDPR, although this is not a valid condition for consent, it is now proposed to regulate in a new sentence 2 that consent to the processing of genetic, biometric or health data (or company and trade secrets) must be given in written form or electronically, unless another form is appropriate due to special circumstances. It follows from the explanatory memorandum of the bill that this would no longer be only a requirement of admissibility but also a requirement of effectiveness: With reference to the opening clause of Art. 9 para. 4 GDPR, a stricter formal requirement would only be necessary for the aforementioned categories of data, in order to maintain the level of protection of the old provision of Section 67b para. 2 sentence 2 SGB X[old version] to the permissible extent. At the same time, the draft law provides that Section 67b para. 3 SGB X is to stipulate for processing for research purposes that a special circumstance under which a deviation from the aforementioned formal requirement is possible exists if the research purpose would be significantly impaired by obtaining written or electronic consent. In this case the reasons should be recorded. What "in writing" according to the SGB X would

mean is not explicitly defined. It is to be assumed, however, that this refers to the requirements of Section 126 BGB.

The requirement of written consent also arises from the AMG, the MPG, the StrlSchV. With regard to the old regulations still applicable here, however, changes are to be expected due to current draft laws.

For logistical reasons, the original paper consent remains at the respective location and only a scan of the document is transmitted in encrypted form to the TTP consent management system.

Is this procedure also legally secure from the point of view of the GDPR?

Article 7 Section 1 GDPR states:

"Where processing is based on consent, the controller shall be able to demonstrate that the data subject has consented to processing of his or her personal data."

In the sense of the principle of accountability (Article 5 Section 2 GDPR) a scan will be sufficient in order to demonstrate that the data subject has consented. In a case as described before it would—from our point of view—already be sufficient if there would be a protocol about the ticking of a box. The more it will be sufficient to have a copy of an original consent form. It would however be advisable to choose a scan-option that does not make use of pattern matching.

As a side note: If the consent form includes personal data, especially data concerning health, the transfer of this data should also be covered by the consent.

How is the use of signature devices, e.g. from sign-o-tec (store biometric data, not only the optical course of the signature) to be seen in relation to the two variants permitted under the German Civil Code (written form requirement or qualified electronic signature)? Under which conditions can Signpads be used hospital-wide for digital collection of the signature and the treatment contract?

German law does not only allow written form or a qualified electronic signature. It would not be necessary to use special signature devices. Therefore one could also use plug-ins for the capture of signatures on mobile terminals or use voice or video recordings of the consenting person.

A major advantage would certainly be that the biometric data could be used to establish a verifiable assignment to the person giving consent. However, such a collection and storage of "biometric data for the purpose of uniquely identifying a natural person" itself is prohibited by Article 9 Section 1 GDPR. The informed consent would also have to cover the processing of biometric data for this reason.

Furthermore, the use of qualified electronic signatures is likely to be ineffective already for practical reasons. According to § 126a para. 1 BGB a signature can be replaced by a qualified electronic signature. However, there will regularly be a lack of the necessary technical prerequisites resulting from the Regulation (EU) No. 910/2014 of the European Parliament and of the Council of 23 July 2014 on electronic identification and trust services for electronic transactions in the internal market and repealing Directive 1999/93/EC (eIDAS Regulation). Article 3 No. 12 eIDAS Regulation defines a "qualified electronic signature" as an

> *"advanced electronic signature that is created by a qualified electronic signature creation device, and which is based on a qualified certificate for electronic signatures".*

Only very few patients, hospitals or study sites will be able to provide corresponding signature generation devices and qualified electronical certificates.

> *When is a consent valid: a) only with signature of the participant or b) only with signature of the participant and signature of the informing person?*

Data protection law does not require any other person than the data subject to give a declaration of consent.

> *Are dates on the consent mandatory?*

The indication of a date is not required by law. However, it is recommendable in terms of the principle of accountability.

> *Is an invalid consent merely a quality defect or must it be a mandatory prerequisite for data collection?*

An invalid consent cannot lead to a lawful processing of personal data based on that consent. However not every mistake leads to an invalid consent. In these cases an individual examination is required.

> *What differences must be taken into account in this regard for AMG or MPG studies compared to "normal" studies within the framework of the professional code of conduct?*

Consent serves different purposes even if the reason for obtaining it usually lies in the protection of the general personality rights. Whenever consent is obtained, it must be informed consent. However, the requirements for the type and scope of information may vary. In all cases there is a risk that incorrect consent will be completely ineffective and that actions that nevertheless take place will be unlawful. However, not every mistake leads to an invalid consent. In these cases an individual examination is required. In general, however, the following can be said:

Medical professional law requires consent with regard to treatment. More specifically, it is a permission for a doctor to intervene in the physical integrity of a patient. Requirements for consent to data processing by a physician, on the other hand, do not arise from the professional codes of conduct of physicians. Only the unauthorised disclosure of patient information by a doctor is covered by the medical confidentiality obligation. This may require consent in the sense of a release from the duty of professional secrecy. Formal requirements are not laid down in the professional regulations of doctors. Also **criminal law** Section 203 StGB does not articulate such requirements. Of course, evidence of the existence of consent is recommended, which is why written consent is often obtained. However, with "normal" studies **data protection law** applies as well. For this we can refer to the above.

Other requirements are sometimes stipulated in specific laws. These include the AMG, the MPG and also the Radiation Protection Ordinance (StrlSchV).

Section 40 para. 1 no. 3 lit. b) **AMG** regulates an informative talk and written consent in medical ethical terms and Section 40 para. 1 no. 3 lit. c) AMG regulates information and written consent in data protection terms. The informative talk has to follow the stipulations according to Section 40 para. 2 S. 1 AMG, which states that the person concerned shall be informed of the nature, significance, risks and implications of the clinical trial **by an investigator** or a **member of the trial group who is a physician** or, in the case of a dental trial, a **dentist**, and of his or her right to terminate participation in the clinical trial at any time, and shall be provided with a generally understandable educational document.

Section 40 para. 2a AMG is concerning the data protection information and lists certain aspects that a participant has to be informed about. In this case the law does not say, that the information has to be provided by a certain person.

Section 20 para. 1 S. 4 No. 2 **MPG** in conjunction with Section 20 para. 2 No. 2 MPG states that the person concerned has to give consent in written form after having had an informative talk with a physician, in the case of medical devices intended for dentistry also by a dentist, about the nature, significance and scope of the clinical trial. The MPG does not distinguish between consent to participation in clinical trials and consent to data processing.

Section 133 **StrlSchV** obliges the radiation protection supervisor (Strahlenschutzverantwortlicher) to ensure that consent is obtained and that information is being provided and an informative talk takes place. Consent in this case covers both the processing of personal data and the use of radioactive substances or ionising radiation on the participants body and examinations that are necessary before, during and after the use of radioactive substances or ionising radiation on the participants body in order to control and maintain his/her health (Section 134 para. 1 S. 1 StrlSchV).

Section 135 para. 1 StrlSchV requires that comprehensible written information is handed out in which the nature, significance, scope and risks of the use of the radioactive substances or ionising radiation are explained and the person involved in the research project is informed of the conditions and duration of the use and of the possibility of withdrawing consent in accordance with Section 134 para. 1 s. 1.

Section 135 para. 2 StrlSchV contains the requirement for an informative talk. The study participant must be informed and questioned by the physician or dentist in charge of the application of radioactive substances or ionising radiation by a doctor or dentist appointed by him whether radioactive substances or ionising radiation have already been applied to him. In the case of applications requiring approval, the physician or dentist in charge must have the necessary expertise in radiation protection. The information shall include the aspects referred to in paragraph 1. The radiation protection supervisor shall ensure that records are kept of the information and questioning.

Are there different validity criteria for consents for the collection and publication/ transfer of data?

Before the GDPR came into force, a distinction was made in the (old) BDSG between collection, processing and use of personal data. After the model of the GDPR this differentiation was largely given up in the German data protection law. A consent, that refers to the processing of personal data, covers therefore all conceivable processing. Special requirements can result for the transmission in countries outside the EU (see article 49 Abs. 1 lit. a) GDPR). Whenever data is transmitted, it must of course be assessed whether this could violate professional secrecy.

In contrast to consent to participate in a study and the related data processing described above, the information about the publication must be explicitly related to this publication. Most laws contain specific provisions for the publications of personal data in the context of scientific research, e.g. Section 27 para. 4 BDSG, Section 13 para. 4 LDSG-SH, Section 37 para. 4 s. 3 LKHG-MV, Section 25 para. 4 BlnLKG. For the study participant it should be pointed out in particular the fact that data can possibly not be taken back after it has been published and an erasure claim may be limited to the right to be forgotten according to article 17 Abs. 2 GDPR.

5.2 Consents (before 25/05/2018)

The TTP administers consents of patients who were collected before 25.05.2018. Individual consents use a passage on the use and transfer of data (including "third countries with lower data protection levels"). A large number of patients have agreed to this passage.

Are these still permissible under Chapter 5 of the GDPR or must new consent be obtained?

How does this regulation behave in particular with regard to cooperations with the USA?

5.2.1 General Information on the Continuation of Declarations of Consent

Consents that were effectively given under the former legal situation generally remain valid. This is the case if a minimum standard has been met so that a core information content existed at the time of consent. Recital 171 GDPR states explicitly:

"Where processing is based on consent pursuant to Directive 95/46/EC, it is not necessary for the data subject to give his or her consent again if the manner in which the consent has been given is in line with the conditions of this Regulation, so as to allow the controller to continue such processing after the date of application of this Regulation."

In recital 42 GDPR it is described as core information content of consents that a declaration of consent pre-formulated by the controller should be provided in an intelligible and easily accessible form, using clear and plain language and it should not contain unfair terms and informs the person concerned at least about who the responsible person is and for which purposes his personal data should be processed. It can therefore be assumed that consent was only given voluntarily if the data subject has been given a genuine or free choice or is able to refuse or withdraw consent without detriment.

However, the fact that the general information obligations and thus the contents of a data protection declaration are changed by the GDPR does not affect the validity of the consent itself. This view is also shared by supervisory authorities.[10]

5.2.2 Third Country Transfer

A third country transfer is a data transfer to a country that does not belong to the European Union or the EEA states. Third Country Transfers are addressed in Chapter V of the GDPR (Article 44 GDPR et seq.).

With regard to the transfer of data to third countries for which no adequacy decision has been taken, the following applies:

In the case of a transfer of a third country, a 2-step-test of legality shall be carried out. In **a first step**, the data controller must ensure that the transfer meets

10 *Bayerisches Landesamt für Datenschutzaufsicht*, Kurzpapier IX—Einwilligung nach der DS-GVO; https://www.lda.bayern.de/media/baylda_ds-gvo_9_consent.pdf.

the general conditions for the processing of personal data. All general requirements of the GDPR are to be met as if it was a processing without reference to third countries. It should be noted though, that a third country transfer may lead to further duties. For example the data subject shall be informed according to Article 13 para. 1f) GDPR about

> *"(...) the fact that the controller intends to transfer personal data to a third country or international organisation and the existence or absence of an adequacy decision by the Commission, or in the case of transfers referred to in Article 46 or 47, or the second subparagraph of Article 49 (1), reference to the appropriate or suitable safeguards and the means by which to obtain a copy of them or where they have been made available."*

In the case of third country transfers, as a **second step** follows in which it is examined whether an adequate level of data protection in relation to the legal framework of the European Union has been achieved in a recipient country or whether suitable or appropriate guarantees have been implemented (Article 45–47 GDPR) or whether one of the exceptions in Art. 49 GDPR is applicable.

Adequacy Decision (Article 45 GDPR)

According to Article 45 GDPR a transfer of personal data to a third country or an international organisation may take place where the Commission has decided that the third country, a territory or one or more specified sectors within that third country, or the international organisation in question ensures an adequate level of protection. Such a transfer does not require a transfer specific authorisation. Only the general requirements of the GDPR have to be met.

At present, a general adequacy decision exists only for the following countries:

- Andorra
- Argentina
- Australia
- Canada (restricted)
- Faroer Islands
- Guernsey
- Isle of Man
- Israel (restricted)
- Japan[11]
- Jersey
- New Zealand
- Switzerland
- Uruguay

11 http://europa.eu/rapid/press-release_IP-19-421_en.htm

There is a special constellation with regard to the **United States of America**: *Although there is no general adequacy decision concerning the US*, American companies have the option of self-certification under the so-called **EU-US Privacy Shield**[12]. *In this case the Commission treats the self-certified companies as if they were in a country with an adequacy decision.*

No Adequacy Decision

In a case where there exists no adequacy decision of the Commission, a controller or processor may transfer personal data to a third country or an international organisation only if the controller or processor has provided appropriate safeguards, and on condition that enforceable data subject rights and effective legal remedies for data subjects are available (Article 46, 47 GDPR) unless one of the derogations for specific situations according to Article 49 GDPR applies.

Appropriate Safeguards

Article 46 para. 2 GDPR states that **without requiring any specific authorisation** from a supervisory authority the following safeguards may be used:

- a legally binding and enforceable instrument between public authorities or bodies;
- binding corporate rules in accordance with Article 47 GDPR;
- standard data protection clauses adopted by the Commission in accordance with the examination procedure referred to in Article 93 (2) GDPR;
- standard data protection clauses adopted by a supervisory authority and approved by the Commission pursuant to the examination procedure referred to in Article 93 (2) GDPR;
- an approved code of conduct pursuant to Article 40 GDPR together with binding and enforceable commitments of the controller or processor in the third country to apply the appropriate safeguards, including as regards data subjects' rights; or
- an approved certification mechanism pursuant to Article 42 GDPR together with binding and enforceable commitments of the controller or processor in the third country to apply the appropriate safeguards, including as regards data subjects' rights.

Also, however **subject to authorisation from the competent supervisory** authority, safeguards may be:

- contractual clauses between the controller or processor and the controller, processor or the recipient of the personal data in the third country or international organisation; or

12 https://www.privacyshield.gov/welcome.

- provisions to be inserted into administrative arrangements between public authorities or bodies which include enforceable and effective data subject rights.

Derogations for specific situations

If the cases mentioned so far are not suitable, the exceptions under Article 49 can also be used. According to Article 49 para. 1 s. 1 GDPR at least one of the following conditions must be met:

- **explicit consent** to the proposed transfer, after having been **informed of the possible risks** of such transfers for the data subject **due to the absence of an adequacy decision and appropriate safeguards**;
- transfer is **necessary for the performance of a contract** between the data subject and the controller or the implementation of pre-contractual measures taken at the data subject's request;
- transfer is necessary for the conclusion or performance of a contract concluded in the interest of the data subject between the controller and another natural or legal person;
- transfer is necessary for **important reasons of public interest**;
- transfer is necessary for the **establishment, exercise or defence of legal claims**;
- transfer is necessary in order to **protect the vital interests of the data subject** or of other persons, where the data subject is physically or legally incapable of giving consent;
- the transfer is made **from a register** which according to Union or Member State law is intended to provide information to the public and which is **open to consultation** either by the public in general or by any person who can demonstrate a legitimate interest, but only to the extent that the conditions laid down by Union or Member State law for consultation are fulfilled in the particular case.

According to Article 49 para. 1 s. 2 GDPR transfer shall also be admissible if the transfer is not repetitive, concerns only a limited number of data subjects, is necessary for the purposes of compelling legitimate interests pursued by the controller which are not overridden by the interests or rights and freedoms of the data subject, and the controller has assessed all the circumstances surrounding the data transfer and has on the basis of that assessment provided suitable safeguards with regard to the protection of personal data. The controller shall inform the supervisory authority of the transfer. The controller shall, in addition to providing the information referred to in Articles 13 and 14 GDPR, inform the data subject of the transfer and on the compelling legitimate interests pursued.

5.2.3 Conclusion

The question of whether declarations of consent obtained before 25 May 2018 continue to be valid must be answered on a case-by-case basis and by examining the complete declaration of consent. A mere reference to a transfer of data to insecure countries may already be uncertain, even under the former legal situation.

In any case, the necessary information on the data processing operations should be provided in an up-to-date form.

5.3 Consent (after 25/05/2018)

> *Does the GDPR permit the following consent clause? What content adjustment would have to be made if necessary?*
>
> *"Pseudonymised data and biomaterials may be transferred to countries for which the European Commission has not determined an adequate level of data protection".*

The above applies accordingly, however, in the case of new declarations of consent to be obtained, the requirements of the GDPR (in particular Article 6, 7, 9 GDPR) must be complied with. The proposed sentence should only be included in a declaration of consent if consent is required for the legitimation of a data transfer to a third country (Article 49 para. 1 s. 1a) GDPR). Otherwise, it is sufficient to provide information within the framework of the data protection declaration, which is made in accordance with Article 13, 14 GDPR.

As far as "biomaterials" are concerned, the data subject does not have to be informed about the transfer to a third country. Biomaterials are not considered personal data under to the GDPR. Even if personal information, in particular genetic data or data concerning health, could be extracted from biomaterials, the biomaterial itself is not considered personal data. Article 4 No. 13 GDPR defines genetic data as

> *"(...) personal data relating to the inherited or acquired genetic characteristics of a natural person which give unique information about the physiology or the health of that natural person and which result, in particular, from an analysis of a biological sample from the natural person in question."*

The wording therefore requires an **analysis of a biological sample** in which data are obtained (see also recital 34).

5.4 Dealing with different consent versions

As part of the study preparations, the declaration of consent for a new study is given to an ethics committee. This committee prepares an ethics vote for the submitted documents in the current version. The TTP assumes that in a study with a valid ethics vote, study participants may only consent to the respective declaration of consent. If the content of a consent changes, it must be voted on again and a new version of the consent must be created accordingly.

If a multicentre study decides to change the content of a consent form, it must in most cases be submitted to all competent local ethics committees. It makes operational sense that uniform versions are always used across all centres. In the case of a version change, the trustee assumes that recruitment must continue with the consent form voted on (e.g. 1.0). Even if the study centre (e.g. Berlin) already has a vote for a newer version (e.g. 1.5), all centres must (according to the previous definition) recruit with the existing and universally voted version (e.g. 1.0) until all centres have a uniformly voted version. What is your legal assessment of this situation? Are study centres allowed to recruit a study with different consent versions at all, or do they have to be uniform throughout the study?

A new ethics vote will only normally be necessary if significant changes have been made. If it makes a difference whether the old version or the new version of the informed consent is used, it should be noted that either all study participants receive and sign the new version of the informed consent, or the research project must be conducted heterogeneously according to the different consents.

There is no universal rule that applies to all areas of scientific research according to which a single ethics vote by a central ethics committee is sufficient. However, there are exceptions for some areas of medical research:

In the field of **clinical trials of medicinal products**, multi-centre studies benefit from simplifications provided for in EU law which have been implemented in national law. In the case of multicentre clinical trials of medicinal products, Article 7 Directive 2001/20/EC provides as follows:

"For multi-centre clinical trials limited to the territory of a single Member State, Member States shall establish a procedure providing, notwithstanding the number of Ethics Committees, for the adoption of a single opinion for that Member State.

In the case of multi-centre clinical trials carried out in more than one Member State simultaneously, a single opinion shall be given for each Member State concerned by the clinical trial."

The first subparagraph of Article 7 Directive 2001/20/EC was implemented in Section 40 para. 1 S. 2 AMG. It states that the ethics committee responsible at

the site of the principal investigator acts as the lead ethics committee and that its vote alone is decisive. According to the second subparagraph of Article 7 Directive 2001/20/EC in an international multi-center study, however, one ethics vote per country is required. It should be noted that **in the future under the 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 (so-called clinical trials regulation—CTR) there will no longer be a comparable provision to Article 7 Directive 2001/20/EC. The regulation of responsibilities will, however, be left to the Member States (see Recital 18 of the CTR).

EU law on **medical devices** does not regulate the competence of ethics committees in multi-centre studies. This applies both to the old EU law with Directives 93/42/EEA, 90/385/EEA and 98/79/EC as well as the new Regulations 2017/745 and 2017/746. Provisions, however, result from Member State law, which provide rules similar to the ones of AMG: Section 22 para. 1 S. 2 MPG stipulates that in the case of a trial conducted by several investigators, the application must be submitted to the independent ethics committee responsible for the principal investigator or head of the clinical trial. Section 22 para. 1 S. 3 MPG expressly states that an ethics vote is sufficient for multicentre studies. According to Section 5 para. 2 S. 2 Ordinance on Clinical Trials of Medical Devices (MPKPV), multi-centre clinical trials or performance evaluation trials conducted by more than one trial site within the scope of the MPG shall be evaluated by the competent ethics committee, with the other ethics committees involved being consulted. Pursuant to Section 5 para. 2 sentence 3 MPKPV, the other ethics committees involved only examine the qualification of the reviewers and the suitability of the review sites in their area of responsibility. The comments made in this regard shall be taken into account. Further information must be documented, but need not be considered by the competent ethics commission (Section 5 para. 2 p. 5 MPKPV).

Furthermore, Section 36 para. 2 S. of the **Radiation Protection Act** (StrlSchG) stipulates that only one ethics vote is required for multi-centre studies. There is no regulation as to which ethics commission would be in charge. The European legal basis of the "Council Directive 2013/59/EURATOM of 5 December 2013 laying down basic safety standards for protection against the dangers arising from exposure to ionising radiation, and repealing Directives 89/618/Euratom, 90/641/Euratom, 96/29/Euratom, 97/43/Euratom and 2003/122/Euratom" contains no provisions on the competence of ethic committees for international multicentre studies beyond the necessity of an ethics committee decision regulated in Art. 55 para. 2 lit. e). However, it can be assumed that this can be determined following the example of the AMG or MPG.

5.5 Withdrawal of a Declaration of Consent/Study Exclusions

Within the scope of the withdrawal process, the data of a participant will be anonymised. The medical data is also locked for further data transfer and can normally not be processed further.

How should this regulation be viewed in connection with AMG/MPG studies? Can data still be supplemented or edited after the withdrawal?

The interaction of GDPR, BDSG and AMG or MPG is complex. The directly applicable GDPR constitutes the basic part of EU data protection law. On the basis of the opening clauses contained in the GDPR, the Member States may in some cases adopt their own data protection regulations. In the case of the processing of health data which is relevant here, the GDPR provides that processing may be carried out either on the basis of a consent pursuant to Article 9 para. 2 lit. a) GDPR, provided that this is not excluded by Member State law, or on the basis of a legal basis of authorisation in Member State law.[13] The opening clauses in Article 9 para. 2 lit. h) GDPR (individual health care), Article 9 para. 2 lit. i) GDPR (public health) and Article 9 para. 2 lit. j) GDPR (scientific research) can be considered for the latter.

The German legislator has provided general regulations on the processing of health data in Section 22 BDSG and Section 27 BDSG for purposes of health care and research. The relationship of the BDSG to other federal laws such as the AMG or the MPG is governed by Section 1 para. 2 sentence 1, 2 BDSG:

"Other federal data protection legislation shall take precedence over the provisions of this Act. If such legislation does not govern a matter conclusively or at all which is covered by this Act, then this Act shall apply."

Specific Sections of AMG and MPG may be considered as other federal data protection legislation in that sense.

For this reason, the data protection related provisions of the AMG and the MPG take precedence over the provisions of the BDSG.

5.5.1 Medicinal Products Act (Arzneimittelgesetz—AMG)

The data protection requirements for the conduct of a clinical trial of a drug in humans are currently regulated in Section 40 para. 1 sentence 3 no. 3c, para. 2a AMG. These national regulations are based in part on provisions of Directive 2001/20/EC on the approximation of the laws, regulations and administrative provisions of the Member States relating to the implementation of good

13 The directly applicable legal bases of Art. 9 para. 2 GDPR are not relevant in the constellations relevant here.

clinical practice in the conduct of clinical trials on medicinal products for human use.

In future, the requirements for clinical trials with medicinal products for human use will be regulated by a directly applicable regulation, namely Regulation 536/2014/EU on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC. Only supplementary regulations are then to be found in Sections 40 etc. AMG-new.

Pursuant to Article 99 of Regulation 536/2014/EU, the Regulation only applies six months after the publication of the notice on the Functioning of the EU Portal and the EU Database referred to in Article 82 para. 3 of Regulation 536/2014/EU in the Official Journal of the European Union. Such notification has not yet been published.

According to Section 40 para. 1 sentence 3 no. 3c AMG, the data protection consent required for conducting a clinical trial—in contrast to the non-data protection consent according to Section 40 para. 1 sentence 3 no. 3b, para. 2 AMG—is indispensable. The inadmissibility of the withdrawal of the data protection consent results from the corresponding information provision of Section 40 para. 2a sentence 1 no. 2 AMG, according to which it must be clarified that the consent according to Section 40 para. 1 sentence 3 no. 3c AMG cannot be withdrawn. This provision, which is primarily concerned with information, also constitutes the inadmissibility of the withdrawal of the declaration of consent.

The aim is to prevent a participant from jeopardising the reliability of the study by subsequently preventing the processing of his data by withdrawing his consent.[14]

The provision of Section 40 para. 1 sentence 3 no. 3c AMG conflicts with Article 7 para. 3 sentence 1 GRPR as well as with Article 13 para. 2 lit. c), Article 14 para. 2 lit. d) and Article 17 para. 3 lit. b) GDPR. In particular Art. 7 para. 3 sentence 1 GDPR determines that the person concerned has the right to withdraw its consent at any time. The legality of any data processing carried out up to that point shall not be affected by such withdrawal.

However, Section 40 para. 2a sentence 1 no. 2 AMG can be justified on the basis of an opening clause in favour of the Member States. The GDPR expressly does not contain an opening clause relating to consent which allows a non-withdrawable form. However, it should be noted that the processing of personal health data is not only possible under Art. 9 para. 2 lit. a) GDPR on the basis of consent, but also without consent in accordance with legal authorisation (cf. Art. 9 para. 2 lit. b) to j) GDPR). The processing of such data after a withdrawal of consent does not therefore necessarily have to be regarded as data processing on the basis of a continuing (non-withdrawable) consent, but could

14 *Rehmann*, AMG, 4. Aufl., 2014, § 40 Rn. 13.

rather be interpreted as data processing without (continuing) consent on the basis of a statutory order. The designation as "non-withdrawable consent" would then only be a legally abridged wording to the effect that certain data processing operations are nevertheless permissible after the withdrawal of consent. The idea of allowing data processing to be carried out on the basis of a statutory regulation becomes clear in the future version of Section 40b para. 6 sentence 3 no. 2 AMG-new. Accordingly, "in the event of withdrawal" of consent, "the stored data may continue to be used" under the conditions specified in the provision.

For the creation of such a legal basis in national law, the Federal legislator can rely on the opening clause of Article 9 para. 2 lit. i) GDPR. The clause enables the Member States to create national regulations which allow the processing of health data for reasons of public interest in the field of public health. In particular, the clause mentions the guarantee of high quality and safety standards for medicinal products as such a public interest. Regulations which permit the processing of health data in the context of a clinical trial even after the withdrawal of consent guarantee the reliability of data from clinical trials (cf. recital 76 of Regulation 536/2014/EU) and serve to reliably determine the effects of the medicinal product to be tested. In the case of lawful data processing using Art. 9 para. 2 lit. i) GDPR, the right of the data subject to have his personal data deleted is also excluded (Art. 17 para. 3 lit. c) GDPR).

In fact on 5th September 2018, the Federal Government passed a draft law on the 2nd Act to Adapt Data Protection Law to Regulation (EU) ("Zweites Datenschutz-Anpassungs- und Umsetzungsgesetz EU—2. DSAnpUG-EU"). With this in particular area-specific data protection regulations are to be adapted to the provisions of the GDPR. Article 18 of the draft also provides for an amendment according to which consent is to be withdrawable under the AMG, but further processing may still remain permissible. The logic represented above would be corresponded with this regulation.

5.5.2 Medical Device Act (Medizinproduktegesetz—MPG)

The possibility to withdraw consent implemented under Section 20 Para. 2 sentence 2 MPG is in line with the compelling regulations of the Art. 7 Para. 3 sentence 1 GDPR as well as the Art. 13 para. 2 lit. c), Art. 14 para. 2 lit. d) and Art. 17 para. 3 lit. b) GDPR. In particular Art. 7 para. 3 sentence 1 GDPR determines that the person concerned has the right to withdraw its consent at any time. A provision stating that personal data already collected may be further processed even after withdrawal does not yet exist. Any further processing of the data would therefore be unlawful. The data must be deleted.[15]

15 Spickhoff/Listl-Nörr, 3. Aufl. 2018, MPG § 20 Rn. 9.

However, Article 83 No. 2 lit. bb) of the 2. DS-AnpUG-EU (Draft law) stipulates that such a right of further processing is to be implemented in Section 20 para. 2 S. 3 MPG-new in the future. According to the draft law, stored data could be to be processed as far as this is necessary to achieve the objectives of the clinical trial or not to seriously impair them or to ensure that the legitimate interests of the data subject are not impaired.

Under the Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC (so-called Medical Device Regulation—MDR), the revocability of consent is governed directly by EU law. Article 62 para. 5 MDR reads as follows:

> *"Any subject, or, where the subject is not able to give informed consent, his or her legally designated representative, may, without any resulting detriment and without having to provide any justification, withdraw from the clinical investigation at any time by revoking his or her informed consent. Without prejudice to Directive 95/46/EC, the withdrawal of the informed consent shall not affect the activities already carried out and the use of data obtained based on informed consent before its withdrawal."*

The same applies under the "Regulation (EU) 2017/746 of the European Parliament and of the Coucil of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU to clinical trials of in vitro diagnostic medical devices" *(so-called IVDR) according to* Article 58 para. 6 IVDR.