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## **Patient information and declaration regarding participation in the "Genome sequencing model project for rare and oncological diseases" in accordance with Section 64e SGB V<sup>1</sup>**

Dear patient,  
Dear parents and legal guardians,

Your physician has offered you<sup>2</sup> the opportunity to take part in a special medical care project, the "Genome sequencing model project" about which we would like to inform you in detail below. The declaration of consent required for this also includes your consent to the performance of genome sequencing and the use of this data to improve care, quality assurance, and evaluation of the model project. We would also like to inform you about the possibility that your patient data might be used for research purposes. Please read the following information thoroughly and take sufficient time to consider your decision and subsequent consent after you have read this information. Please note that your self-determination rights also include the right not to know about findings from genetic data. If you have any uncertainties or questions (or if you require further information), please contact the physician treating you. You will also find relevant contact details on the last page of this document.

Your participation in the model project is voluntary. If you do not fully agree with the nature and long-term duration of the use of your data as described below or if not all of your questions have been answered to your satisfaction, you should not declare your participation. However, you have the option of cancelling your participation and withdrawing your given consents at any time.

In the following, we would like to provide you with some general information about the **genome sequencing model project (GenomSeq)**, your options for participation, and the use of your data in the model project. If you are interested in participating in this project, you can confirm your participation by signing the enclosed declaration.

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<sup>1</sup> Verso2\_PatInfo\_TE\_MV\_GenomSeq\_ZPMU\_EN

<sup>2</sup> For the sake of simplicity, we are using the direct form to address both patients and their legal guardians, parents and caregivers.

## 1. General information

Genomic medicine can help to significantly improve the diagnosis and treatment of certain diseases. As part of the model project, patients with rare diseases or cancer will be examined for genetic changes that may cause the disease. This will enable **early and more precise diagnosis, the use of personalised therapies, and early disease prevention for those affected.**

Furthermore, an increased risk for a rare disease or cancer can be determined for those affected, thus contributing to early prevention and diagnosis.

### Genomic medicine Info Box



**DNA** - a thread-like molecule with the structure of a twisted rope ladder that carries genetic information and thus the blueprint of cells and living organisms, occurs in the nucleus of every human cell.

**Gene** - section of DNA that contains very specific information (e.g. for building a specific protein). The human genome contains well over 20,000 such genes.

**Genome** - the entirety of the genetic information of an organism (e.g. a human being), is generally identical for all cells in our body. The human genome of each cell consists of 46 individual DNA molecules ("chromosomes"), on which the genes are distributed.

**Genome sequencing** - technical process for decoding the sequence of DNA building blocks in a specific section of the genome or across the entire genome.

**Genomic data** - the sequence of DNA building blocks in the analysed regions of the genome, determined by genome sequencing, can refer only to individual genes or gene segments, or to the entire genome.

**Clinical data** - collection of patient data that is important for medical care, e.g. age, sex, place of residence, diagnosis, data on the severity of the disease, and the course of treatment.

**Personalised therapy** - treatment method tailored to the individual person. In the context of genomic medicine, the analysis of genetic markers through genome sequencing, for example, can help those treating the patient to select an effective and safe therapy for the person concerned.

**Pseudonymisation** - a measure by way of which personally identifiable data (e.g. name, date of birth) is replaced by a pseudonym (e.g. a randomly appearing character string such as "AT1LLA42XFULD4\_4EVR") in order to make it more difficult or practically impossible to determine the identity (of patients).

Source: Federal Institute for Drugs and Medical Devices (BfArM); image source: genomDE model project, funding code 2521DAT80; TMF e.V. coordination centre, agency: Sympathiefilm GmbH

The GenomSeq model project also includes the **collection and linking of genomic and clinical data** for the purpose of improving care, quality assurance<sup>3</sup>, evaluation<sup>4</sup> of the model project and scientific research<sup>5</sup>. A cross-linked analysis of genomic and clinical data from many patients at different locations is expected to provide new insights. It should then be possible to provide patients with individual, tailored, i.e. personalised treatment recommendations on the basis of this knowledge. Personalised therapy is not always available at present; however, the aim is to make it possible in the future. The GenomSeq model project is also intended to improve the care of patients with rare and oncological diseases.

It is possible that analysis of the data from patients at different locations may show that two illnesses appear to be similar cases. In such a situation, a professional exchange and contact between the treating physicians may become necessary. This would be the case, for example, if - according to the clinical-diagnostic assessment of the enquiring doctor - the treatment of another patient requires a professional exchange and contact with the doctors treating you. The results of your genetic analysis may be communicated as part of this professional exchange. Your personal data will only be viewed by medical staff who are obligated to maintain confidentiality and who are in charge of your case. Your identity will not be disclosed to the requesting organisation.

In order to enable this contact between treating physicians, your **consent to case identification for professional exchange between treating physicians** (see declaration of participation, page 11, point 1.1) is required. **Participation in the model project is also possible without this consent.**

Furthermore, it is possible that research using data from the model project may yield results that could be of considerable importance regarding your health. Especially if a serious, possibly previously unrecognised illness is suspected or if there is a new treatment option for you, you may be informed so that further steps can be discussed. In addition, there may be **further analytical results and incidental findings** that could be relevant to your health and further treatment and about which we would like to inform you. You can decide for yourself whether we may contact you in this context, as you have a **right not to know**. The extent to which these results could have consequences for your relatives would be discussed with you in a separate consultation with a specialist in human genetics, including human genetic counselling in accordance with the German Genetic Diagnostics Act (Gendiagnostikgesetz).

Your **consent to the re-identification of your data and to being contacted in the event of a new finding in the course of the research** (see declaration of participation, page 12, point 1.2) is required in order for us to contact you with information related to findings discovered. **Participation in the model project is also possible without this consent.**

Should you wish to allow the use of your data in research, we ask you to confirm this in the attached **consent to having your data used for scientific research** in a separate document, unless you have already agreed to this use at an earlier time. Further information on the possible use of your data for research purposes can be found in chapter 4. **However, participation in the model project is also possible without this consent to having your data used for scientific research.**

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<sup>3</sup>The quality of data collection and processing will be reviewed by those involved in the GenomSeq model project. This concerns both the retrieval of clinical data on site at the clinics and the collection and secure processing of genomic data in the respective data centres

<sup>4</sup>The evaluation of the model project is ultimately intended to clarify the added value of the technologies and analysis methods used for the diagnosis and treatment of patients and thus serves to improve medical care in the future.

<sup>5</sup>Separate consent is required for the use of your patient data in research (see chapter 4).

## 2. How will my participation proceed?

The GenomSeq model project involves quality-assured and standardised diagnostics as well as personalised treatment identification using genome sequencing and the necessary data processing. Genome sequencing means analysing the exact sequence of nucleotides (i.e. the building blocks of DNA) in a person's genome (see Info Box on page 2). The resulting genomic information can provide insight as to the presence of particular genetic characteristics that can trigger or sustain certain diseases.

Genomedical care in the model project is provided specifically in compliance with the **German Genetic Diagnostics Act** and data protection regulations. The German Genetic Diagnostics Act stipulates that a genetic examination or analysis may only be carried out and a genetic sample may only be obtained if you, as the person concerned, have consented towards the physician in charge expressly and in writing to the required examination and collection of the genetic sample. If you have not already given your consent, you will be informed about the nature, significance, and scope of the genetic test by your physician before you give your consent.

Before genome sequencing is performed, a comprehensive review of your diagnostic and therapeutic options will be carried out in a case conference among several medical experts in order to ensure that genome sequencing is a suitable diagnostic method for you. If this review comes to the conclusion that genome sequencing is not a suitable option in your case, or that the necessary genetic tests do not fall under the scope of the German Genetic Diagnostics Act (e.g. sequencing of tumour tissue), the need for separate information and consent according to that Act will no longer apply.

As part of genomic diagnostics, it is generally necessary to first take blood and/or tissue samples, for which you must give your consent to the treating physician. Provided the German Genetic Diagnostics Act applies to your situation, your prior consent towards the responsible doctor, as stipulated by the Act and described above is also required.

The results of the genetic test will be discussed by several medical experts within the framework of a case conference, and a report shall be drawn up summarising the results and, if possible, containing a diagnosis or treatment recommendation.

Once the examination and analyses have been completed (typically within a few weeks), your doctor will provide you with the results of the genome sequencing analysis. Based on this, the clinical significance of the findings will be explained to you and the next steps will be discussed with you, unless you have agreed otherwise with your physician.

Depending on your personal situation, you will receive genetic counselling before the genetic test and/or after the test results are available, e.g. also on the subject of early detection measures or regarding the implications of the findings for your relatives.

In Abhängigkeit von Ihrer persönlichen Situation werden Sie vor der genetischen Untersuchung und/oder nach Vorliegen der Untersuchungsergebnisse humangenetisch beraten, z.B. auch zum Thema Früherkennungsmaßnahmen oder zu den Auswirkungen der Befunde für Ihre Angehörigen.

### 3. How will my data be processed and used as part of the model project?

#### Which data will be processed?

In the GenomSeq model project, data for analysing your genetic information (your "genome"), data on your diagnosis, and on the further course of treatment of your disease will be collected and used for the purpose of improving care, quality assurance, and evaluation of the model project.<sup>6</sup>

The data sets include **clinical data** (age, sex, place of residence, diagnosis, data on disease severity, and course of treatment) as well as **genomic data** generated during DNA sequencing (i.e. the exact sequence of DNA building blocks in the respective regions of your genome analysed).

#### How and where is the data stored?

**Clinical data** is stored in a so-called "clinical data node". This is either operated by the institution you are treated in or by another institution involved in the GenomSeq model project (usually a university hospital).

**Genomic data** is so unique that it can only ever be assigned to a single person. By linking this data with other personal characteristics, you can be identified directly. Therefore, in order to protect your personal rights, your genome data is stored separately from other personal characteristics that identify you (such as your name) and is protected by technology. Your genomic data generated in the course of genome sequencing is therefore stored in a so-called "genome data centre".

Prior to this storage in clinical data nodes or genome data centres, the identifying personal characteristics are replaced by an apparently random character string (i.e. "pseudonymised"). This means that your identity is no longer immediately recognisable. This **pseudonymisation** is carried out by a trust centre at the Robert Koch Institute (RKI). The list that allocates the character strings to the real names remains with the trust centre.

Your data will also be pseudonymised temporarily directly at the hospital when your data is transmitted to the clinical data node or the genome data centre by the hospital treating you. The nature of this temporary pseudonymisation is based on the RKI's specifications. This pseudonym is deleted after transmission. Furthermore, the data is also transmitted in encrypted form.

These measures (separation of genomic data from your other personal characteristics, pseudonymisation, encryption of data transmission) are intended to prevent direct identification of your person and to significantly increase the protection of your data.

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<sup>6</sup> In accordance with Article 6(1)(a) and (b), Article 9(2)(a), (h) and (i) GDPR, Section 630a BGB, Section 64e SGB V, where applicable in conjunction with Section 8(1) sentence 3 GenDG.

Currently, the model project is planned for 5 years, although the structures established for this aim could be merged to a permanent operation and the data be made available for long-term use for the purposes described above. The objective of the project is to ensure that aspects of genomic medicine are incorporated into standard medical care in the future. Subject to your consent, your data can therefore be stored for up to 100 years (see below). **Here, too, you naturally have the option of exercising your right to object (see declaration of participation, page 12, chapter 2).**

### How will the data be used?

Your data will be used exclusively by officially authorised users<sup>7</sup> for the above-mentioned purposes. Access to the data collected in the model project is defined precisely by law: The Federal Institute for Drugs and Medical Devices (BfArM)<sup>8</sup> assumes the role of the so-called "platform provider" in the model project, i.e. the authority is responsible for the approval and control of the data centres (clinical data nodes and genome data centres), which form the "data platform" for storing the data. In order to control utilisation of the data, the BfArM operates an application portal through which official applications for data utilisation can be submitted. In a precisely defined procedure, the platform operator checks the authorisation of the applicants to use your data. Only if the application is approved will the BfArM provide the applicants with the required data for the above-mentioned purposes in a secure working environment and in pseudonymised form. In most cases, the applicants will be physicians, scientists from public research institutions (universities, research institutes) and research-based companies. A current overview of the participating sites, research projects, and authorised users in the model project can be found on the BfArM website<sup>9</sup>. Your data will be deleted at the latest after 100 years.

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<sup>7</sup> The authorised users and the conditions of use are set out in Section 64e (11) SGB V.

<sup>8</sup> The BfArM is an independent higher federal authority within the portfolio of the German Federal Ministry of Health.

<sup>9</sup> [https://www.bfarm.de/DE/Das-BfArM/Aufgaben/Modellvorhaben-Genomsequenzierung/\\_node.html](https://www.bfarm.de/DE/Das-BfArM/Aufgaben/Modellvorhaben-Genomsequenzierung/_node.html)



#### 4. Collection and use of your data for scientific research

As part of your diagnosis, treatment, and participation in the GenomSeq model project, patient data will be collected from you. This patient data can be of considerable value for medical research. Research is necessary in order to continuously improve the early detection, treatment, and prevention of diseases. Insights gained from your patient data and biomaterials can potentially contribute a great deal to this. Your data can be used for **scientific research** provided you give your separate consent to this.<sup>10</sup>

With the research consent form you have been given, you not only authorise the use of your data for scientific research within the GenomSeq model project, but you also give your **general consent to the use of your health data for scientific research**. If you give your consent for your data to be used for scientific research, the data can be made available to universities, research institutes and research companies for medical research purposes **upon request**. The legitimacy of each individual research project with your patient data is reviewed in advance by an independent Ethics Committee and requires its favourable assessment. Please refer to the separate document on research consent for more information.

**If you do not fully agree with this extensive use of your data for research purposes, you should not give your consent to research use.**

**In the model project itself**, the use of your data for scientific research is regulated by the BfArM in accordance with the legal requirements and is only authorised after a positive assessment in an application procedure. The BfArM checks the applicant's authorisation to use your data and provides the necessary data. Your data will only be used without direct reference to your person (i.e. in pseudonymised form). For the pseudonymisation of your data, a separate trust centre has been set up for the model project, which is operated by the Robert Koch Institute. For reasons of transparency, the research projects approved as part of the model project and their results are regularly published on the BfArM website.

In order to make the use of genomic data feasible for research purposes, it must be analysed together with your clinical data. Special data nodes have been established for this purpose, which store and process your clinical and genomic data separately and only in pseudonymised form without direct reference to your person. When processing and analysing genomic data, it may not be possible to delete your data immediately if you withdraw your consent and your data can no longer be removed from analyses that have already been started. This is due to technical reasons and cannot be prevented with reasonable effort.

If you would like to authorise the general use of your data in scientific research, please confirm this in the enclosed separate document with your consent. **Please only give your consent if you agree to the comprehensive use of your data for scientific research.**

**Your consent to the use of your data for scientific research is voluntary. Participation in the model project is also possible without this consent. If you do not give your consent, you will not suffer any disadvantages in the context of your treatment. You have the right to withdraw this consent at any time.**

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<sup>10</sup> In accordance with Article 6(1)(a), Article 9(2)(a) GDPR.

## 5. Data protection information

In accordance with the General Data Protection Regulation (GDPR), at any time and towards all parties involved in the model project who process your personal data (see last page of this document) you have the right

- to receive information about your processed data in accordance with Article 15 GDPR,
- to have your personal data corrected (Article 16 GDPR) if it is not stored correctly,
- to restrict the processing of your data if the requirements of Article 18 GDPR are met,
- to arrange for your data to be transferred to another institution of your choice (Article 20 GDPR), and
- to arrange for deletion (Article 17 GDPR), provided this is legally permissible and does not conflict with statutory record-keeping periods.

The persons responsible for processing your patient data and the respective data protection officers and their contact details are listed on the last page of this document.

You have the option of lodging a complaint with any data protection supervisory authority. You will find the competent supervisory authority for the institution treating you on the last page of this document.



## 6. Where can I get more information?

Information provided by the Federal Ministry of Health on the topics of personalised medicine and genomic medicine can be found here:

<https://www.bundesgesundheitsministerium.de/en/en/international/european-health-policy/genomde-en.html>

Here you can find the **BfArM**'s official website on the genome sequencing model project:

[https://www.bfarm.de/EN/BfArM/Tasks/Model-Project-Genome-Sequencing/\\_node.html](https://www.bfarm.de/EN/BfArM/Tasks/Model-Project-Genome-Sequencing/_node.html)

The following link will take you to an explanatory film<sup>11</sup> by the genomDE initiative<sup>12</sup> on the subject of genome sequencing and the model project:

<https://bit.ly/3XJCWtW>

Here you can find an explanatory film on Patient declaration of Consent for medical research purposes (Broad Consent):

<https://www.uniklinik-ulm.de/zpmu/onkologische-erkrankungen/fuer-patienten.html>

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<sup>11</sup> Pilot project genomDE, funding code 2521DAT80; coordination centre TMF e.V., agency: Sympathiefilm GmbH

<sup>12</sup> <https://www.genom.de/de#>

## 7. Contact persons and contact details

### **Centre for Personalised Medicine Ulm (ZPM)**

Albert-Einstein-Allee 23  
89081 Ulm

#### **Speaker ZPM Ulm:**

Prof. Dr. med. Thomas Seufferlein  
PD Dr. med. Verena Gaidzik (representative)

#### **Office ZPMU**

Phone: 0731 500-44754  
Email: [zpm.ulm@uniklinik-ulm.de](mailto:zpm.ulm@uniklinik-ulm.de)

#### **Homepages:**

[www.uniklinik-ulm.de/zpm](http://www.uniklinik-ulm.de/zpm)  
[www.zpm-verbund.de](http://www.zpm-verbund.de)  
[www.dnpm.de](http://www.dnpm.de)

The person responsible for data processing pursuant to Art. 4 para. 7 GDPR is Ulm University Hospital (Ulm University Hospital, 89070 Ulm, [info.allgemein@uniklinik-ulm.de](mailto:info.allgemein@uniklinik-ulm.de)). The person internally responsible for data processing in this project is Prof. Dr T. Seufferlein, University Hospital Ulm, Albert-Einstein-Allee 23, 89081 Ulm, Tel.: 0731-500-44501. If you have any questions about the collection or use of your data, please contact him, your medical contact at Ulm University Hospital or the ZPM office (Nadine Karmen, Centre for Personalised Medicine, Ulm University Hospital, Albert-Einstein-Allee 23, 89081 Ulm, Tel.: 0731-500-44754).

If you have any concerns or complaints with regard to data protection or wish to exercise your rights in accordance with Art. 15 et seq. of the GDPR, please contact Ulm University Hospital, Data Protection Officer, Albert-Einstein-Allee 29, 89081 Ulm, email: [dsb.ukl@uniklinik-ulm.de](mailto:dsb.ukl@uniklinik-ulm.de), phone: 0731/500-69290. You also have the right to lodge a complaint with the competent supervisory authority for data protection (State Commissioner for Data Protection and Freedom of Information in Baden-Württemberg, P.O. Box 10 29 32, 70025 Stuttgart, phone: 0711 / 61 55 41 716, email: [Poststelle@lfdi.bwl.de](mailto:Poststelle@lfdi.bwl.de)).

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## **Declaration regarding both participation in the genome sequencing model project for rare and oncological diseases as well as consent to the performance of genome sequencing**

### **1. Declaration of participation in the genome sequencing model project and consent to the performance of genome sequencing and the associated data processing**

I<sup>13</sup> have received patient information on the genome sequencing model project in accordance with Section 64e SGB V and I have been informed about the model project and about the nature, significance, and implications of genetic testing, have understood this, and have had sufficient time to consider my decision.

**I would like to participate in the model project and consent to genome sequencing and the processing of the collected genomic and clinical data for diagnostic or therapeutic purposes, in order to improve care, quality assurance, and evaluation.**

☐ Yes      ☐ No

**Note: Participation in the model project is not possible without this consent.**

#### **1.1 Consent to professional exchange between treating physicians, if necessary, combined with case identification**

It is possible that expertise of colleagues from other sites will need to be sought for optimal diagnosis and treatment. In the course of this professional exchange, colleagues could be informed of the results of your<sup>14</sup> genetic test.

In justified cases, the trust centre can re-establish the link to your treatment case. Such a case exists e.g. if, according to the clinical-diagnostic assessment of the enquiring doctor, the treatment of another patient requires a professional exchange and contact with the person treating you, as your cases are similar. Your personal data will only be viewed by medical staff who are obligated to maintain confidentiality and who are in charge of your case. Your identity will not be disclosed, as the professional exchange takes place with pseudonymised data.

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<sup>13</sup> For the sake of simplicity of the document, the pronoun I includes both patients capable of giving consent and those not capable of giving consent (minors or those in care).

<sup>14</sup> For the sake of simplicity, we are using the direct form to address both patients and their legal guardians, parents and caregivers.

For this purpose, I release my attending physician from his/her duty of medical confidentiality and consent to the cross-site exchange of my data and if necessary, to the re-identification of my case data via the trust centre.

☐ Yes ☐ No

**Note:** Participation in the model project is also possible without this consent.

### 1.2 Consent to re-identification of your data and to being contacted in the event of a new finding in the course of the research

It is possible that research using data from the model project may yield results that could be of considerable importance regarding your health. Especially if a serious, possibly previously unrecognised illness is suspected or there is a new treatment option for you, you may be informed so that further steps can be discussed.

In addition, there may be further analytical results that could be relevant to your health and further treatment (additional findings). You can decide whether we may contact you in this context, as you have a right not to know. Please note that you may have to disclose health information that you receive through such feedback to other bodies (e.g. before taking out health or life insurance) which could result in disadvantages to you. As information from your genetic material ("genome") is to be used for medical research in addition to the clinical data, the information may also relate to your genetic predisposition to certain diseases. The extent to which these results could have consequences for your relatives would be discussed with you in a separate consultation with a specialist in human genetics.

For this purpose, I consent to the re-identification of my data via the trust centre and to being contacted again by my attending physician.

☐ Yes ☐ No

**Note:** Participation in the model project is also possible without this consent.

### 2. Right to terminate participation and right to withdraw consent

I have been advised that I can terminate my participation in the model project in writing with effect in the future at any time and without giving reasons either towards the person treating me or the institution supervising me in the model project and that the data collected and stored will be deleted when I leave the model project. I am aware and understand that cancelling my participation and/or withdrawing my consent will not result in any disadvantages for me in the context of conventional treatment.

Termination does not affect the lawfulness of the processing previously carried out on the basis of the declaration of consent regarding participation in the model project until cancellation. Data that is further processed for your diagnosis and treatment may be subject to statutory record-keeping periods and will only be deleted after these have expired.

### **I have been advised that I can revoke my given consent**

- 1.1 (Consent to case identification for professional exchange between treating physicians, if necessary, combined with case identification) and
- 1.2 (Consent to re-identification of your data and to being contacted in the event of a new finding in the course of the research)

in writing with effect in the future at any time and without giving reasons either towards the person treating me or the institution supervising me in the model project.

Withdrawal of consent does not affect the lawfulness of the processing previously carried out on the basis of your consent given before its withdrawal. The withdrawal of consent has no effect on your participation in the model project and the performance of the genetic tests.

If you wish to terminate your participation in the GenomSeq model project or withdraw your consent, please get in touch with the contact points on the last page of the patient information.

### **3. Signatures**

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**Surname and first name of the patient or legal representative in block letters**

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**Date, signature of the patient or legal representative<sup>15</sup>**

**Note for privately insured persons:**

If available, please enter your **health insurance number**:

If you do not yet have a health insurance number, please request one from your health insurance company and send it to [zpm.ulm@uniklinik-ulm.de](mailto:zpm.ulm@uniklinik-ulm.de) as soon as possible.

You can find all Private Health Insurances participating in the model project here: <https://www.pkv.de/verband/ueber-uns/mitglieder-pkv-verband/>

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**Date, name in block letters and signature of the informing physician**

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<sup>15</sup> In the case of minors, both legal guardians must sign or present appropriate powers of attorney.