**Template**

**For informed consent of parents/custodians of minors concerning the use of biological samples and related data of minors in biobanks**

Recommended by the Permanent Working Party of the German Medical Ethics Committees
approved by the General Assembly on 07/11/2019

***Information for users of the template (to be deleted in the final document)***

If two individuals have the care and the custody of the minor concerned, consent must be obtained from both parents/custodians.

Informing the minor may only take place, if the parents/custodians have been informed beforehand by a physician in an oral discussion, and in principle consider allowing the minor to participate in the biobank. If the parents/custodians decide that the minor should **not** participate in the biobank then the minor should not have to concern her-/himself with this issue and should not receive any information in this regard.

A legally effective consent to participate in the biobank can only be given by parents/custodians who have been previously informed. If the minor is able to understand the relevance and the consequences of his/her participation in the biobank and is thus, able to express his/her will, consent should also be obtained from the minor. Although minors younger than 14 years are in general not able to give their consent, his/her refusal must nevertheless be respected. The signature of a minor does not represent a legally binding consent, but rather demonstrates that the minor does not refuse to participate in the biobank.

Furthermore, the general rules, recommendations and instructions (printed in red and italics) laid down in the preliminary notes (preface) of the “Template for informed consent concerning the use of biological samples and related data in biobanks” approved by the General Assembly on 21/06/2019 are valid and in effect.

**Dear parents/dear custodian(s)!**

Thank you very much for taking the time to read this information leaflet.

The examination of human biosamples and the analysis of the related data - including analytical data obtained from the biosamples - are important instruments in medical research. To understand diseases, it is essential to learn more about the underlying biological processes. For example, we now know that the genetic make-up of an individual, i.e his or her genes play a pivotal role in the development and treatment of diseases. **For this reason we would like ask our patients, in this case, your child or *the minor in your care,* and you as parents/custodians, whether you are willing to provide us with certain biological samples and data for research purposes**. Biological samples such as blood, urine or tissue will be collected and stored in a so-called biobank and linked to the related medical data. The biobank presented here is operated by *[name of biobank organisation/institutional host/legal representative of the biobank/client]*.

Please take all the time you need to reflect on whether you agree to the use of the biological samples and related data of *your child/ (the minor in your care)*. We also encourage you to discuss your thoughts on the matter with *your child/ (the minor in your care)*.

An age-appropriate explanation and an oral discussion of the matter with your child/the minor in your care will only take place, if you as parents/custodians have been informed beforehand by a physician, and in principle, are considering allowing *your child/ the minor in your care* to participate in the bio­bank. In this case, we will also ask *your child/ the minor in your care* for his/her own intention if he/she is old enough. If he or she is unwilling, participation in the biobank will not be possible.

**Your consent to the use of the donated biological samples and related data of *your child/ the minor in your care* is voluntary. If you or *your child /the minor in your care* do not wish to participate or wish to withdraw the given consent later, neither you nor *your child/ the minor in your care* will suffer from any reprisal.**

In the following, we would like to inform you about the objectives of the biobank as well asthe procedures and the measures that are in place for the protection of the personal data of *your child/ the minor in your care*, so that you can form your own opinion and decide on that basis.

**1. What are the aims of the biobank?**

The biobank serves to foster medical research. To this end, the collected human biological samples and related data are to be stored long-term and shall support medical research in order to improve the prevention, diagnosis and treatment of diseases. **The aim of this research is neither to make a diagnosis for your child/ the minor in your care or for any other individual, nor is it intended to provide evidence of individual predispositions that may cause diseases.** Rather, the comparative analysis of larger patient groups or population-cohorts will serve to identify general biomedical relationships.

Biological samples from children will be used exclusively for medical research issues that cannot be addressed solely with biosamples from adults.

The orientation of the biobank in question should be stated briefly and concisely (e.g. main areas of research, cohorts/population of donors addressed).

**2. What type of human biological samples and data are collected?**

Here, only tissue specimens, blood and urine are referred to. If a biobank is intended for the storage and use of other human biological samples (e.g. liquor, saliva, swabs, stool), the text should be adapted accordingly.

The collected biological samples are tissue specimens and body fluids that are removed during the current hospitalization/physician’s examination or treatment of *your child /the minor in your care*but are no longer needed and would otherwise be destroyed. *If applica­ble*: In addition, during a routine venepuncture, we would like to collect supplementary blood samples for medical research [exact type and amount of blood/urine or other samples that are collected]. The data collected includes selected information about *your child/ the minor in your care* in particular medical data [specify further data that may be required, e.g. genetic data].

If biological samples are also to be obtained during future hospital or study visits or routine medical visits of the child/minor (e.g., outpatient departments), this must be described. The same applies if data of the child/minor are to be collected during future visits.

**3. How are the human biological samples and data used?**

Broad donor consent is only possible under certain conditions. In particular, it would only be requested from donors if it were necessary for objective reasons. For example, this would be the case, if, due to the orientation of the biobank, a limitation to certain disease areas, specific research purposes or examination methods is not possible.

Variant 1 (specific consent): The biological samples and data donated by *your child/ the minor in your care* will be used exclusively for research on the following diseases / for the following research areas [...] However, the exact questions cannot be clearly specified at this moment. As far as applicable: **It is possible that the biological smples of *your child/ the minor in your care* will also be genetically tested, possibly including an analysis of his/her whole genetic material (or “whole genome”).**

Variant 2 (broad-based consent): **We will ask you and *your child /the minor in your care* for very broad-based permission to use the biological samples and data of *your child/ the minor in your care*. These will support medical research on improvement of the prevention, detection and treatment of diseases. They will be used for a wide range of medical research purposes in the interest of maximizing the benefit to the general public.** This may relate to specific disease areas (e.g. cancer, cardiovascular diseases, diseases of the brain, etc.) as well as to diseases and genetic relationships that are still currently unknown. Because new questions are constantly arising in research, the biological samples and data of *your child/ the minor in your care* may also be used for medical research projects that cannot be foreseen today. The biological samples and data of *your child/ the minor in your care* will not be used for research projects that are deemed unethical by the ethics committee that evaluates the project (see below, point 7e).

If applicable: **It is possible that the biological samples of *your child/ the minor in your care* will also be genetically tested, possibly including an examination of his/her whole genetic material (or “whole genome”).**

Either: You and *your child/ the minor in your care* have the right to make individual limitations in your declaration of consent (e.g. the exclusion of certain research, the exclusion of passing on the biosamples to third parties).

Or: For logistical reasons, it is not possible for the biobank to ensure individual limitations (e.g. exclusion of certain research, exclusion of the transfer of the biosamples to third parties). If you and *your child/ the minor in your care* do not fully agree with the manner and duration of use described here, you should not give your consent.

Sample retention for an indefinite period of time may only be requested from donors if this is necessary for objective reasons, for example because the future research purposes for which the biological samples are stored are not yet known with sufficient accuracy or the achievement of the research purpose would otherwise be endangered (e.g. in the case of rare diseases). In this case, it must be ensured that the necessity for the further storage of the biological samples and data is reviewed at regular intervals.

Either: The donated biological samples and related data will be stored for up to [...] years. At the latest, the biological samples will be destroyed and the personal data deleted after this time has elapsed.

Or: The donated biological samples and related data will be stored for an indefinite period of time and made available for medical research. [Please state reasons].

**4. What risks are associated with the donation of biomaterials/data by your child/the minor in your care?**

**a. Health risks**

Variant 1 (only left-over samples are used): Since we only want to use human biological samples for the biobank, which are removed within the scope of the diagnostic or therapeutic measures planned for *your child/ (the minor in your care)* and which would normally be destroyed as residual samples, the donation is not associated with any additional health risk for *your child/ (the minor in your care)*.

Variant 2 (additional biological samples are removed during a routine intervention): In the case of *your child/ (the minor in your care)*, a routine venipuncture is planned for diag­nostic or therapeutic reasons / for study purposes. Within this routine blood sampling, we would like to take an additional [...] ml of blood (this corresponds to approximately/less than [...] tablespoons). The physician taking the blood samples will ensure that the amount of blood and the procedure itself is not associated with any additional health risk for *your child/ (the minor in your care). [Attention: the treating physician must ensure that the procedure is tenable on an individual basis!]*

Adapt accordingly for the collection of other biological samples. For research projects with strictly research-related blood sampling and/or other invasive measures as additional inter­vention(s), a separate specific information and a specific consent are required.

**b. Other risks**

Any collection, storage and transmission of data from *your child/ the minor in your care* in the context of research projects involves confidentiality risks (e.g. the possibility of identi­fying *your child/ the minor in your care*), especially with regard to genetic information contained in biological samples of *your child/ the minor in your care*. These risks can­not be completely eliminated and increase the more the data can be linked, especially if you yourself or *your child/ the minor in your care* publish genetic data in the Internet (e.g. for genealogical research). Under point 7 "Who has access to your biosamples and data?" we explain in more detail how the privacy of *your child/ the minor in your care* is protected.

**5. What are the personal benefits for your child/ the minor in your care?**

**You cannot expect any immediate personal benefit or advantage for the health of *your child/ the minor in your care* from the donation of his/her biosamples and data. Their analysis is for medical research purposes only, and not to draw conclusions about the health of *your child/ the minor in your care*.**

**However, it is possible in individual cases that a researcher may conclude that a result could be of considerable importance for the health of *your child/ the minor in your care*. This is particularly the case if there is a suspicion of a serious, previously possibly undetected disease that could be treated or whose onset could be prevented. In such a case you may be contacted (see point 9 below).** Please note, however, that you may be required to disclose health information obtained by such a feedback to other authorities (e.g. before contracting a health or life insurance for *your child/ the minor in your care*) which may result in potential disadvantages.

If genetic analyses are planned: Since tests of the genetic material/genes of *your child/ the minor in your care* are also possible/planned, the above text may also refer to the genetic predisposition for certain diseases. Such genetic information can also have an impact the family members of *the child/ the minor in your care* and his/her future family planning.

**6. What are the benefits for the general public?**

Medical/scientific research projects aim to improve our understanding of how diseases develop and how they are diagnosed and, on this basis, to improve treatment and prevention strategies/options. If applicable: Further/More detailed information on the activities of the [biobank] can be found under [homepage specified].

**7. Who has access to the biosamples and data of of your child/ (the minor in your care), and how are they protected?**

**a. Coding of human biological samples and data**

All data that directly identify *your child/ (the minor in your care)* (name, date of birth, address, etc.) are replaced by a code (so-called pseudonymised) immediately after the biosamples have been taken. [If - as should generally be the case – this is intended: Thereafter, the data sets are either re-coded and stored directly or re-coded at latest when the biosamples are released]. Only in this (double-coded) form, are the biosamples and related data issued for medical research purposes.

The data identifying *your child/ the minor in your care* directly remain in the institution where the biosamples and data were obtained. Here, they are stored separately from the biological samples and the related medical data. The biosamples and data can therefore not be attributed personally to *your child/ the minor in your care* without the cooperation of this institution. In such cases, an assignment will only be made to add new data from the medical records of *your child/ the minor in your care* or to make contact with you or *your child/ the minor in your care* if you have agreed to be contacted (see point 9 below). **Identifiable data of *your child/the minor in your care* will not be disclosed to researchers or other un­authorised third parties such as insurance companies or employers.**

In the above passage, it is assumed that the biobank does not receive any personally identifying data. These should remain in the institution (hospital/physician) where the data were obtained. If a different procedure is intended, this must be made clear.

**b. The transfer of biological samples and data**

If a transfer of biosamples and data is planned: The encoded biosamples and related medical data are hosted by [biobank/hospital], but for specific medical research purposes may also be transferred to other institutions such as universities, research institutes and companies/industry conducting medical research within the EU but also outside the EU, according to pre-defined rules. In this process, the data of *your child/ the minor in your care* may also be linked to medical data from other databases if the legal requirements are met. Biosamples and data released to researchers may only be used for the intended research project and may not be disclosed by the recipient for any other purposes. Unused human biological samples will be returned to the source biobank or destroyed, as stipulated by that biobank.

**c. Transfer to countries outside the European Union**

Your biosamples and data may also be transferred to recipients in countries outside the EU if one of the following conditions are met:

* The European Commission has determined that the country in question has an adequate level of data protection,

or, if this has not been done,

* The [responsible body of the biobank] agrees contractual data protection clauses with the research partners that have been enacted or approved by the European Commission or the competent supervisory authority. You can obtain a copy of these data protection clauses from [the responsible body of the biobank].

Under theses conditions a transfer of biosamples and data is legally allowed, because European and National law consider the measures taken for data protection in that country as adequate. **Nevertheless, there is a certain risk that public or private bodies may access the data of *your child/ the minor in your care*, although this would not be permitted under the European data protection regulation. It is also possible that you or *your child/ (the minor in your care)* may have fewer or less enforceable rights of access, and that there is no independent supervisory authority to assist you in exercising your rights.** **In this case, the biosamples and data of *your child/ the minor in your care* can only be passed on if you have expressly agreed to this, and the above-mentioned conditions are met. To agree to these conditions, you can tick the appropriate box in the consent form.**

You can withdraw your consent for the transfer of biological samples and related data at any time without giving reasons and without reprisal for you or for *your child / (the minor in your care)*. In the same manner, *your child/ the minor in your care* can withdraw his/her agree­ment for the transfer of biosamples/data at any time. In that case – independent of other (pre-)conditions for data-transfer – no further data will be passed on to countries outside the EU.

**d. Evaluation by an Ethics Committee**

If broad-based consent is intended (cf. “handbook” no. 2b): The main prerequisite for the use of human biological samples and related data in a specific medical research project is, as a rule, that the research project has been previously evaluated and approved by an inde­pen­dent ethics committee.

**e. Publications**

Results of medical research obtained with your biosamples and/or related data are only published in an anonymised fashion, i.e. in a form that does not allow any conclusions about the identity of *your child/ the minor in your care*. If genetic tests are planned: This applies in particular to genetic information. However, it is possible to make genetic information on *your child/ the minor in your care* available in specially protected scientific databases, which are not accessible to the general public.

**8. Do you or your child/ the minor in your care or the biobank derive a financial benefit from the use of the biosamples and data from your child/ the minor in your care?**

With the transfer of the human biological samples to [name of legal entity of the biobank], they become the property of [name of legal entity of the biobank]. You also authorise [name of legal entity of the biobank] to use the (related) data of *your child/ the minor in your care*.

You or *your child/ the minor in your care* will receive no remuneration for the donation of the biosamples and data. If a commercial benefit is obtained from medical research by using the biosamples or data, you or *your child/ the minor in your care* will not be a beneficiary.

The biobank uses the biosamples and data of *your child/ the minor in your care* exclusively for medical research purposes. The biosamples and data will not be sold. If applicable: However, the biobank may charge users an appropriate fee for the provision of the (quality-controlled) biosamples and data.

**9. Will you or your child/ (the minor in your care) be contacted again?**

a. Particularly for participants in childhood and adolescence it is meaningful to collect further follow-up data, so that you and *your child/ the minor in your care* may be contacted again later to request additional information and/or biological samples. In addition, the renewed contact can be used, for example, to obtain your consent and the consent of *your child/ the minor in your care* to link his/her data to medical data from other databases.

Please tick in the consent form whether or not you wish to be contacted again in such cases.

b. In rare cases a researcher may conclude that a research result may be be of considerable importance for the health of *your child/ the minor in your care* (see point 5 above). In such cases, the results will be communicated to you, or to *your child/ the minor in your care*, when she/he has reached maturity (his/her legal age).

Explain by whom [custodian of the biobank or medical institution] and in what manner [in writing / by telephone] it is intended to contact whom [patient/proband/treating hospital physician/study physician/general practitioner].

c. Within one year after reaching his/her maturity (legal age) we will directly contact *your child/ the minor in your care* to give him/her the opportunity of making his/her own decision on the future use of his/her biological samples and related data. To accomplish this we will ask you for the current contact details of *your mature* *child/ the mature person previously in your care,* or if necessary, we will make use of publicly available sources of information.

If within one year after an attempt to contact *your mature child/ the mature person pre­viously in your care*, we do not get a response, still hosted (unused or remaining) bio­samples and related data can be used only in an anonymised form. Anonymisation means that the identification code, which could be used to identify the person from whom the biosample or data was obtained, has been deleted, (see above point 7a/b). However, such anonymisation of biological samples can never completely rule out the possibility that the genetic data might later be assigned to *your (mature)* *child/ the (mature) person previously in your care.*

**10. What does your right of withdrawal include?**

**You can withdraw your consent for using the biological samples and related data *of your child/ the minor in your care* at any time without giving reasons and without reprisal for you or *your child/ the minor in your care*. In the same manner, *your child/ the minor in your care* can withdraw his/her agreement.**  However, the legality of the use of the biosamples and data collected up to the the revocation remains unaffected.

In case of withdrawal, the biological samples will be destroyed and the data deleted. However, data can only be deleted if this is possible with reasonable technical effort. In addition, data from analyses already carried out cannot be removed (particularly, if already published).

Instead of destroying the biosamples or deleting the data, you and *your child/ the minor in your care* can also agree that your biosamples or data may be used in an anonymised form for medical research purposes. Anonymisation means that the identification code is deleted (see above point 7a/b and 9c). However, such anonymisation of biosamples can never completely rule out the possibility that the genetic material might later be assigned to *your (mature)* *child/ the (mature) person person previously in your care* by using other sources of information. As soon as the anonymisation has been carried out, a targeted destruction of such biosamples or deletion of such data is no longer possible.

Please contact us in case you wish to withdraw: [Name, address, contact details of contact person/biobank organisation].

**11. What other data protection rights do you and your child/ (the minor in your care) have?**

The legal basis for the processing of the data of *your child/ (the minor in your care)* is your consent according to Articles 6(1)(a) and 9(2)(a) of the General Data Protection Regulation.

The person responsible within the meaning of the General Data Protection Regulation is [the responsible body of the biobank and - if separate from it - of the data collecting institution with contact data].

You and *your child/ the minor in your care* can request information from [the responsible body of the biobank and the data collecting institution] regarding the data stored about you within the framework of the legal requirements. You and *your child/ the minor in your care* can also request that incorrect data be corrected, that the data you and *your child/ the minor in your care* have provided be transferred, and that the data be deleted or its processing restricted. To exercise these rights, you and *your child/ the minor in your care* can contact [competent body of the institution of the data collecting body].

If you have any concerns regarding data processing and compliance with data protection, you and *your child/ the minor in your care* can also contact the (institutional) data protection officer: [Functional address of the data protection officer of the data collecting institution and - if separate - of the biobank].

You and *your child/ the minor in your care* also have a right of appeal to any data protection supervisory authority. A list of the supervisory authorities in Germany can be found at

https://www.bfdi.bund.de/DE/Infothek/Anschriften\_Links/anschriften\_links-node.html

**12. Where can you and your child/ (the minor in your care) get more information?**

If something remains unclear to you, please ask your treating physician or your study physician before you give your consent. You can also contact [...] later for further questions.

**Please read the following declaration of consent carefully, tick the appropriate boxes and then sign at the end of the consent form if you agree.**

**Declaration of consent (parents/custodians)**

Patient/proband (surname, first name): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Date of birth: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

I have read the information document and had the opportunity to ask questions. I know that the participation of *my child/ the minor in my care* is voluntary and that I and my child/ *the minor in my care* can withdraw consent at any time without giving reasons and without any reprisal.

I agree that the biological samples and related data of *my child/ the minor in my care*, as described in the information document, may be given to [name of biobank organisation] and used for the medical research purposes mentioned in the information document. In particular, **I agree that, as described in the information document,**

* **[institution/place of recording] collects personal data of my child/ the minor in my care, especially information about his/her health, takes further personal data from the medical records of my child/ the minor in my care if necessary, and stores the data in a pseudonymized form (i.e. coded);**
* **the biosamples are stored in a pseudonymised form by [biobank organisation/ host institution or legal body of the biobank/client]. In the name of my child/ the minor in my care I transfer the ownership of the biosamples to [name of legal body of the biobank organisation];**
* **the biosamples with the above-mentioned data may be transferred in a pseudo­nymised formform to universities, research institutes and companies/industry conducting medical research, for the purposes of medical research.**

**If applicable: Under certain circumstances, this also includes the transfer of pseudo­nymized biosamples and/or data for research projects in countries outside the EU. This is generally permissible if the European Commis­sion has made a ruling on the adequacy of data protection or if officially approved data protection clauses are applied.**

**I consent to the transfer of the pseudonymized biosamples and/or data to countries outside the EU under the aforementioned conditions. I have been informed about the possible risks of such a transfer (point 7c in the information).**

□ Yes □ No

If this option is offered in the parent/custodian information (point 3): I would like to restrict the use of the biosamples and data of *my child/ the minor in my care*in terms of subject matter or time as follows

.................................................

**I agree that my child/ (the minor in my care) and I may be contacted again at a later date**

- for the purpose of obtaining further information / biosamples,

 □ yes □ no

- for the purpose of obtaining my consent to link the data of *my child/the minor in my care* with medical data from other databases,

 □ yes □ no

- for the purpose of providing feedback on important health-related results

 □ yes □ no

In addition, *my mature child/ (the mature person previously in my care)* or I can be contacted again if – exceptionally - important health-related results emerge. The institution, where the bio­samples/data were obtained or the following physician (if desired, please specify) should give this feedback.

Name and address of physician ­­­­­­­­­­­­­­­­­­­­\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Moreover, my child/ the minor in my care will be contacted after reaching maturity (legal age) to give her/him the opportunity of making his/her own decision on the future use of his/her biological samples and related data.

**I have received a copy of the parent/custodian information and the consent form. The original remains with the [institution/place or name of biobank organisation].**

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Name of one parent/custodian in block letters

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Place, date (to be entered by the parent/custodian), signature of the first

parent/custodian

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Name of the other parent/custodian in block letters

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Place, date (to be entered by the parent/custodian), signature of the second parent/custodian

I have conducted the clarification interview and obtained the consent of the parents/custodians of the minor.

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Name of the person providing information in block letters

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Place, date, signature of the person providing information