**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 discussed the matter beforehand with a physician, and in principle agree to allow 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 will 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 biological samples, also referred to as biosamples, and 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) plays a pivotal role in the development of a disease and in the corresponding choice of treatment. **For this reason, we would like ask our patients, in this case, your biological child or the minor in your care – hereafter referred to as *your child* – and you as parents/custodians, whether you are willing your child 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*. We also encourage you to discuss your thoughts on the matter with *your child*

An age-appropriate explanation and an oral discussion of the matter with your child will only take place, if you as parents/custodians have been informed beforehand by a physician, and in principle, are considering allowing *your child* to participate in the biobank. In this case, we will also ask *your child* 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* is voluntary. If you or *your child* do not wish to participate or wish to withdraw the given consent later, there will be no negative consequences for you or *your child.***

In the following, we would like to inform you about the objectives of the biobank as well as the procedures and the measures that are in place for the protection of the personal data of *your child*, 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 promote medical research. To achieve this, the human biosamples collected and the corresponding medical data of the patient are to be stored on a long-term basis and will 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* 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,*but are no longer needed and would otherwise be disposed of.

*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* 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 unavoidable, for example, if the orientation of the biobank does not allow a limitation to certain disease areas, specific research purposes or examination methods.

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

Variant 2 (broad-based consent): **We will ask you and *your child* for very broad-based permission to use the biological samples and data of *your child*. These will support medical research on improvement of the prevention, detection and treatment of a wide range of diseases, thus 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* may also be used for medical research projects that cannot be foreseen at present. The biological samples and data of *your child* will not be used for research projects that are deemed unethical by the evaluating ethics committee (see below, point 7e).

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

Either: You and *your child* 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* 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 areas for which the biosamples are stored have not yet been delineated in detail, or the achievement of the research goals would otherwise be compromised (e.g. in the case of rare diseases). In this case, it must be ensured that the necessity for further storage of the biological samples and data is reviewed at regular intervals.

Either: The donated biosamples 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 biosamples/data by *your child*?**

**a. Health risks**

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

Variant 2 (additional biological samples are removed during a routine intervention): In the case of *your child*, 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 [...] 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. [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* in the context of research projects involves confidentiality risks (e.g. the possibility of identifying *your child*), especially with regard to genetic information contained in biological samples of *your child*. These risks cannot be completely eliminated and increase the more the data can be linked, especially if you yourself or *your child* 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* is protected.

**5. What are the personal benefits for *your child*?**

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

**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*. This is particularly the case if there is a suspicion of a serious, possibly previously 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 obtaining a health or life insurance policy for *your child*) which may result in potential disadvantages.

If genetic analyses are planned: Since analyses of the genetic material/genes of *your child* are also possible/planned, the above text may also refer to a genetic predisposition for certain diseases. Such genetic information can also have an impact on the family members of *the child* 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 *your child*, and how are they protected?**

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

All data that directly identify *your child* (name, date of birth, address, etc.) are replaced by a code immediately after the biosamples have been taken. This is referred to as pseudo­nymisation. [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 released for medical research purposes.

The data that directly identify *your child* 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* 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* or to make contact with you or *your child* if you have agreed to be contacted (see point 9 below). **Identifiable data of *your child* 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 data that allows the identification of a particular subject. 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* 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**

The biosamples and data of *your child* 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*, although this would not be permitted under the European data protection regulation. It is also possible that you or *your child* 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* 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 biosamples and related data at any time without giving reasons and without negative consequences for you or for *your child*. In the same manner, *your child* 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 the biosamples of *your child* and the related data will only be published anonymously, i.e. in a form that does not allow any conclusions about the identity of *your child*. If genetic tests are planned: This applies in particular to genetic information. However, it is possible to make genetic information on *your child* available in specially protected scientific databases, which are not accessible to the general public.

**8. Do you, *your child*, or the biobank derive a financial benefit from the use of his/her biosamples and related data?**

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] the use of the related data of *your child*.

You or *your child* 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* will not be a beneficiary.

The biobank uses the biosamples and data of *your child* 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* 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* 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* 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 to the health of *your child* (see point 5 above). In such cases, the results will be communicated to you or to *your child,* when he/she 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 he/she has reached maturity (legal age) we will directly contact *your child* to give him/her the opportunity to make 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,* 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* we do not get a response**, unused or remaining biosamples still in storage and the 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.*

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

**You can withdraw the consent for the use of the biosamples and related data *of your child* at any time without giving reasons and without negative consequences for you or *your child*. In the same manner, *your child* can withdraw his/her agreement.** However, the legality of the use of the biosamples and the data collected up to the the retraction of consent remains unaffected.

In case of withdrawal, the biosamples will be destroyed and the data deleted. However, the 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* can also agree that the 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* 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* have?**

The legal basis for the processing of the data of *your child* 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* 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* can also request that incorrect data be corrected, that the data you and *your child* have provided be transferred, and that the data be deleted or its processing restricted. To exercise these rights, you and *your child* 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* 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* 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* get more information?**

If something remains unclear to you, please ask your treating physician or 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* is voluntary and that *my child* and Ican withdraw consent at any time without giving reasons and without any negative consequences.

I agree that the biosamples and related data of *my child*, 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*, especially information about his/her health, takes further personal data from the medical records of *my child* if necessary, and stores the data in a pseudonymised 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* 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 form to universities, research institutes and companies/industry, 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 of *my child* 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*in terms of subject matter or time as follows

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

**I agree that *my child* 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* with medical data from other databases,

 □ yes □ no

- for the purpose of providing feedback on important health-related results of *my child.*

 □ yes □ no

In addition, *my mature child* or I can be contacted again if, in exceptional cases, 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:

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Moreover, *my child* will be contacted after reaching maturity (legal age) to give him/her 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].**

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Name of one parent/custodian in block letters

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Place, date (written by the parent/custodian), signature of the first parent/custodian

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Name of the other parent/custodian in block letters

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Place, date (written 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.

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Name of the person providing information in block letters

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Place, date, signature of the person providing information