**Template**

**For informed consent of adolescents (12-17 years old) concerning the use of biological samples and related data 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)***

The adolescent will only be informed, if the parents/custodians have discussed the matter beforehand with a physician and in principle agree to allow the adolescent to participate in the biobank. If the parents/custodians decide that the adolescent should **not** participate in the biobank then the adolescent will not have to concern him-/herself 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 adolesent 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 adolescent. 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 an adolesent does not represent a legally binding consent, but rather demonstrates that the adolescent agrees to participate in the biobank. Any unwillingness of the adolescent must be respected.

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 10/06/2016 are valid and in effect.

**Dear patient,**

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

To improve the treatment of diseases, a lot of research remains to be done. For this purpose, we have to analyse large numbers of human biological samples such as blood, urine and tissue samples. These are called “biosamples”. We use such samples to learn more about the various diseases. **For this reason we would like ask you, whether you are willing to provide us with certain biosamples and information on your health (“health data”) for research purposes**.

Biosamples and related data of all participant patients will be collected and stored in a so-called “biobank”.

Please take all the time you need to reflect on whether you agree to the use of your biosamples and related data. We also encourage you to discuss the matter with your parents. **Your consent is voluntary. If you do not wish to participate or wish to withdraw the given consent later, there will be no negative consequences.**

With the following information, you can form your own opinion and make your descision on that basis. However, you may only participate if your parents agree to it.

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

The biobank serves as a collection of biosamples and makes them available to researchers. This research is aimed at improving the prevention, diagnosis and treatment of a variety of diseases. You can find more information under (indicate www/homepage biobank).

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

During your treatment, blood or other biological samples are routinely collected and analysed. The remaining material would normally be disposed of. Instead of discarding, these biosamples remain, and are stored in our biobank. The collected samples comprise [type and amount of blood/urine or other samples that are collected].

*If applicable*: In addition, we would like to collect an extra amount of blood [exact amount of exta-blood (in spoons)] if a routine blood sampling planned, so that no extra needle-prick is necessary.

To make optimal use of your donated biosamples in medical research, your health-data are also very important, in particular data on the course of your disease [specify further data that may be required, e.g. genetic data].

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

Variant 1 (specific consent): Your donated biological samples and data will be used exclusively for research on the following diseases / for the following research areas [...].

As far as applicable: **Within the scope of this research it is [also possible/very probable] that a genetic analysis will be performed on one or more biosamples. Your genetic material is inherited from your biological parents and is present in every living cell of your body. It consists of many genes which together encode the construction plan and regulate the function of your body. They can also play a significant role in the development of many diseases.** If applicable: **The analysis may target single known genes or possibly your entire genetic material (or “whole genome”)** **if the genes relevant to our research have yet to be identified.**

Variant 2 (broad-based consent): Your donated biological samples and data will be used for a wide range of medical research purposes. This may relate to many different diseases as well as to diseases that are still currently unknown. As far as applicable: **Within the scope of this research it is [also possible/very probable] that your genes (or genetic material) will be analysed. Your genetic material is inherited from your biological parents and is present in every living cell of your body. It consists of many genes which together encode the construction plan and regulate the function of your body. They can also play a significant role in the development of many diseases.** If applicable: **The analysis may target single known genes or possibly your entire genetic material (or “whole genome”)** **if the genes relevant to our research have yet to be identified.**

If applicable: You have the right to make individual limitations in your declaration of consent e.g. the exclusion of certain research.

Either: **The donated biological samples and related data will be stored for up to [...] years. Thereafter, the biosamples will be disposed of and the data deleted.**

Or: **The donated biological samples and related data will be stored as long as they are relevant for (medical) research. Therefore, it is currently not possible to determine, when the biosamples will be disposed of and the data deleted.**

**4. What are the risks associated with the donation of your biological samples and data?**

**a. Health risks**

The collection of biological samples is not associated with any additional health risk for you.

**b. Other risks**

Because we store (personal) data from you, we cannot completely rule out that unauthorised persons may gain access to these data and thus acquire personal information about you and your disease. This risk increases if you publish personal information, particularly your genetic data, in the Internet (from e.g. ancestry analysis companies) or in Social Networks/Media. Under point 7 "How are your biosamples and data protected?" we explain in more detail how we will protect your privacy.

**5. What are your personal benefits?**

You cannot expect any immediate personal benefit or advantage for your health from the donation of your biosamples and related data. The biobank serves to support medical research and not your individual treatment or care.

However, in rare cases, a researcher may conclude that a resultcould be of relevance to your health. In this event, we will contact your parents/custodians.

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

Medical research on your biological samples may contribute to a better understanding of how diseases develop and how to treat them.

**7. How are your biosamples and (related) data protected?**

Your biological samples and health data are not identified using your personal data (name, date of birth, address, etc.) but are replaced by a code (e.g. “XG72jdk784”).

Data that allow you to be identified remain in the [Institution], where they are stored sepa­rately from the biological samples and the related medical data. **They will not be passed on to third parties. Thus, researchers analysing your biosamples will not see your name, but only the relevant code. In addition, if the research results are published, for example in scientific journals or the Internet, your name will never be disclosed.**

If a transfer of biosamples and data is planned: The encoded biosamples and related medical data (as described above) may also be transferred to other research institutions in this country and abroad. In this regard, your parents/custodians have received more detailed information. If applicable: In countries outside the EU it is possible that yor data are less protected than in our country (e.g. Germany). In this case, a transfer can only take place with your agreement.

**8. Do you have a financial benefit?**

If you donate your biological samples to us, they become the property of [name of legal entity of the biobank]. However, you will receive no money for your donation.

**9. Will you be contacted again?**

It is possible that you and your parents/custodians will be contacted again later, e.g. to request additional information and/or biological samples. In any event, we will contact you again when you reach maturity (your legal age). This gives you the opportunity to make your own decisions on the further use of your donated biosamples and related data.

**10. Can you change your decision?**

**Your participation in the biobank is completely voluntary. You can withdraw your consent for using your biosamples and related data at any time without giving reasons and without any negative consequences.**

In case of withdrawal, you can decide if the biological samples should be disposed of and the data deleted, or if they may be used further in an anonymised form. “Anonymisation” means that the identification code for your biological samples and related data has been deleted, so that neither can be assigned to you anymore. However, because biological samples may comprise genetic information, such anonymisation can never completely rule out the possibility that somebody may accidentally ascertain their origin by other means.

Please contact us in case you wish to withdraw: [Name, address, contact details of contact person/biobank organisation].Your parents may, of course, also withdraw their consent.

**11. What other data protection rights do you have?**

Because we process and store your personal data, the General Data Protection Regulation applies. The processing of your data is therefore only permitted with your consent.

The person (or institution) responsible for the processing of your data is [the responsible body of the biobank and - if separate from it - of the data collecting institution with contact data].

You can request information from [the responsible body of the biobank and the data collecting institution] regarding the data stored about you. You can also request that incorrect data be corrected, that the data you have provided be transferred, and that the data be deleted or its processing restricted. To exercise these rights, you can contact [competent body of the institution of the data collecting body].

If you have any concerns regarding the processing and protection of your data, you 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].

In addition, you 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 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 [name, address, contact details of the biobank] later for further questions. More information can be found under (indicate www/homepage biobank).

**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 (adolescent 12-17 yrs.)**

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

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

Information on parents/custodian(s)

Surname, first name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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

Surname, first name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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

I have read the information document and had the opportunity to ask questions. I know that my participation is voluntary and that I can withdraw my consent at any time without giving reasons and without any negative consequences.

I agree that my biological samples and related data, as described in the information document, may be given to [name of biobank organisation] and may be used in coded form for the medical research purposes described in the information document.

**If applicable:** I also agree that my coded biological samples and related data may be transferred to countries outside the European Union (EU).

□ Yes □ No

If this option is offered in the information document (point 3): I would like to restrict the use of my biosamples and data in terms of subject matter or time as follows

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

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

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

Name of adolescent patient in block letters

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Place, date (written by the adolescent patient), signature adolescent

**I have conducted the clarification interview and obtained the consent of the adolescent patient.**

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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