**Template**

**For informed consent of minors (7-11 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 30/09/2020

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

The minor will only be informed, if the parents/custodians have discussed the matter beforehand with a physician, and in principle agree to 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 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 previously been informed. Minors in the age- group addressed here are not considered able to give their consent. Thus, the signature of a minor does not represent a legally binding consent, but rather demonstrates that the minor agrees to participate in the biobank. The signature is not a prerequisite for participating in the biobank and should only be requested, if – following the assessment by the informing physician/person – the minor appears to be able to cope with a “formal” declaration of agreement. However, any unwillingness on the part of the minor 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 ……………………!** (first name of the child)

We would like to ask you, if you wish to participate in our biobank. Your descision to participate or not can be made together with your parents, after reading this information leaflet, which serves to explain everything about our biobank.

**1. What is a biobank?**

Although doctors and scientists already know a lot about human diseases, much needs to be discovered and many difficult problems still need solving until we can fully understand what makes us ill. The process of solving these problems is called medical research. Medical researchers are working to improve our knowledge of many diseases, so that we can understand them and so find better treatments and cures.

To do this, medical researchers need to examine biological samples, or “biosamples” as they are usually called, from as many people as possible who have a particular disease. These biosamples may be blood, saliva, urine or other samples from the body. While it may seem strange to you that blood, saliva or urine are so valuable, they contain many clues about what is going wrong in your body when it has a disease. These clues can be studied in a laboratory using, for example, a microscope or chemical tests.

YOU can help these medical researchers by allowing us to take your biosamples and keep them in a facility called a “biobank“. A biobank is really a building that contains many very large freezers that keep a great number of biosamples frozen, so that they can be stored for a long time until they are needed.

**2. Who gets the biosamples?**

Before they are frozen, the biosamples are divided up into very small portions, which can be made available to different researchers for their investigations. It is under­stood that we pay particular attention to the people who request samples from our biobank. We also store your biosamples very carefully in large freezers and guard them attentively, so that they are kept as secure as possible

In addition to the biosamples, we also collect and store some personal information on you (e.g. your age and your disease). However, your name is always kept secret, because your biosamples and your information are encoded with a number before storage. Thus, nobody - except your treating doctor and his closest team - will know your true name. This is of course also the case for all researchers who are allowed to use your biosamples.

**3. Whom does the biobank serve?**

Often it takes many years before new medicines are finally developed and on the market. If you participate in our biobank, you will probably have no immediate benefit. However, scientific research on your biosamples could perhaps contribute to helping other people in the future.

**4. How can I participate/contribute?**

It is possible that some blood has been taken from you in previous medical examinations. Alternatively, during an operation (surgery) some tissue samples, such as skin, have been removed. Normally, any remaining material from these samples would be simply discarded. However, here we are asking for your permission to keep these remaining samples in order to store them in our biobank and use them for medical research. Because we use existing leftover materials, no extra sample collection or needle-prick is needed.

*If applicable*: In addition, if a routine blood sampling is intended, we would like to collect some extra blood. Again, in this case, no extra needle-prick is needed. [Please adapt to other kinds of biosamples, if applicable].

**5. How can I make my decision?**

If you agree to our storing your biosamples in a biobank and using them for medical research, either you can tell us personally or you can sign this information leaflet.

**Very important: The decision, as to whether you want to donate your biosamples or not, depends entirely on you and on your parents/custodians. After all, these are YOUR biosamples!**

If you do not want your biosamples to be stored in our biobank and to be used for medical research, there will be no negative consequences. Our main concern is your wellbeing. For us, your decision on donating your biosamples or not, is not crucial!

If you change your mind, you are free to tell us at any time that you do not want your personal information and biosamples to be stored in our biobank and used for medical research. This decision will have no negative consequences for you. In this case, your stored biosamples will be discarded and all of your personal information deleted.

We are glad, that you have taken the time to read this information leaflet and to inform yourself on our biobank!

If you need any more information or details, please, feel free to contact us whenever you like. Perhaps yor parents/custodian(s) may also provide some more information.

You may sign now on the following page, if you would like to participate.

**Declaration of agreement (minors 7-11 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 would like to participate and donate my biological samples to the biobank.**

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

Signature of minor (optional)

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

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

Name of the person providing information in block letters

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

Place, date, signature of the person providing information