Template

For informed consent 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 21/06/2019

The following template for patient/proband information refers to biological samples (or biospecimen) collections for medical research, i.e. collections of human biological samples and related data (hereinafter: biobanks), regardless of their size, project relevance or other categories (i.e., study- or desease-specific). It contains the aspects essential for information and consent and represents a formulation aid. The text is to be adapted to the needs, special features and orientations of the respective biobank. In particular, specifications are to be made wherever possible. In addition, reference is made to the "Recommendations of the Working Group of Medical Ethics Committees for the evaluation of research-related biobanks by ethics committees" ("Handbook") in the version of 10 June 2016.

The information must be provided in an oral discussion by a physician or staff member trained specifically for biobanks. The physician or another appropriately qualifed individual (WMA-Declaration Fortaleza, 2013) must then seek the potential subject's freely-given informed consent, preferably in writing.

All passages printed in red and italics are instructions for the individual adaptation of the text and are to be deleted from the form to be handed over to the participants - as are any alternatives that may have been formulated.

Letterhead (address/contact person) of the institution collecting the biosamples and related data, including the data controller].

Patient/proband information

Dear patient/dear research participant,

The examination of human biosamples and the analysis of the related data including analytical data obtained from the biosamples have become important instruments for medical research. To understand diseases, it is essential to learn more about the underlying biological processes. For example, we now know that genetic materials (genes) play a pivotal role in the development and treatment of diseases. That is why we would like to ask you as a patient/research participant, whether you are willing to provide us with certain biological samples and data for research purposes. The biological samples such as blood, urine or tissue shall be collected in a so-called biobank and linked to the related medical data. The here presented biobank is operated by [name of biobank organisation/institutional host/legal representative of the biobank/client].

Your consent to use your donated biological samples and related data is voluntary. If you do not wish to participate or wish to withdraw your consent at a later date, you will not suffer from any reprisal.

In the following explanations, we would like to inform you about the objectives of the biobank, the procedures and the measures taken for the protection of your personal data so that you can make 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 made available for medical research in order to improve the prevention, diagnosis and treatment of diseases. **The aim of this research is not to make a diagnosis, neither for your person nor for any other individual, nor 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.

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/biosamples and data are collected?

Here, only tissue specimen, blood and urine are referred to. If a biobank wants to collect and use other human biological samples (e.g. liquor, saliva, swabs, stool), the text should be adapted accordingly.

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

For research participants: The biological samples [...] that are to be taken [if applicable: additionally] from you for medical research purposes are [exact type and amount of blood/urine or other samples that are collected]. . The data collected includes information about your person, 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 (e.g., out-patient departments), this must be described. The same applies if data 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 is 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): Your donated biological samples and data will be used exclusively for the research on the following diseases / for the following research areas [...] However, the exact questions cannot yet be clearly specified at this moment. As far as applicable: **It is possible that your biological smples will also be genetically tested, possibly including an analysis of your whole genetic material (or "whole genome").**

Variant 2 (broad-based consent): **We will ask you for very broad-based permission to use your donated biological samples and data. They will be made available for medical research in order to improve the prevention, detection and treatment of diseases. It will be used for a wide range of medical research purposes in the interest of maximizing the benefit to the general public.** It 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 unknown today. Because new questions are constantly arising in research, your biological samples and data may also be used for medical research projects that cannot be foreseen today. Your biological samples and data 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 your biological samples will also be genetically tested, possibly including an examination of your whole genetic material (or "genome").**

Either: You have the right to make individual limitations in your consent form (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 do not fully agree with the here described fashion and duration of use, you should not give your consent.

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 it is checked at regular intervals whether further storage of the biological samples and data is still necessary.

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

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 are the risks associated with your donation?

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 anyway within the scope of the diagnostic or therapeutic measures planned for you and which would normally be destroyed as residual samples, the donation is not associated with any additional health risk for you.

Variant 2 (additional biological samples are removed during a routine intervention): In your case, 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). This add-on collection of blood samples is not associated with any additional health risk for you.

Adjust accordingly for the collection of other biological samples.

Variant 3 (an additional procedure is required for sample collection):
We would like to take [...] ml of blood (equivalent to about [...] tablespoons). This is associated with the low risks of a normal routine venipuncture. Pain may occur at the puncture site or bruising may occur. In extremely rare cases, a blood clot (thrombosis) may form, a localised inflammation may occur at the puncture site or permanent damage to blood vessels or nerves may occur.

For the removal of other biological samples - as far as it is permitted - adapt accordingly.

b. Other risks

Any collection, storage and transmission of data from your biological samples in the context of research projects involves confidentiality risks (e.g. the possibility of identifying your person), especially with regard to information on your genetic material. These risks cannot be completely ruled out and increase the more data can be linked, especially if you yourself 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 your privacy is protected.

5. What are the benefits for you personally?

Personally, you cannot expect any immediate benefit or advantage for your health from the donation of your biosamples and data. Their analysis is for medical research purposes only and <u>not</u> to draw conclusions about your health.

However, it is possible in individual cases that a researcher may come to the conclusion that a research result could be of considerable importance for your health. This is particularly the case if there is suspicion of a serious, previously possibly undetected disease that could be treated or whose outbreak could be prevented. In such a case you may be contacted (see point 9 below).

Please tick in the consent form whether you would like or not to get feedback in such a case (see also point 9 below). You can change your decision for or against a feedback option at any time by notifying us. Please note, however, that you may be required to disclose health information obtained by such a feedback also to other authorities (e.g. before contracting a health or life insurance) which may result in potential disadvantages for you or even your family members.

If genetic analyses are planned: Since tests of your genetic material/genes are also possible/planned, the above text may also refer to your genetic predisposition for certain diseases. Information on your genes can also have an impact on your family members and general 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 your biosamples and data, and how are they protected?

a. Coding of your biological samples and data

All data that directly identify your person (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 - foreseen/established: Thereafter the data sets are recoded and stored either directly or at latest when the biosamples are released]. Only in this (double-coded) form the biosamples and related data are issued for medical research purposes.

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

The above passage assumes that the biobank does not receive any person-identifying data; rather these 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 envisaged/planned: The encoded biosamples and medical data are hosted by [biobank/hospital], but for specific medical research questions/ issues may also be transferred to other institutions such as universities, research institutes and companies/industry conducting medical research within the EU according to pre-defined rules. In this frame, your data 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 purpose and may not be disclosed by the recipient for any other purposes. Unused human biological samples will be returned to the providing 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].

[If applicable:] In addition, it may occur that biosamples and data shall be passed on to research partners in third countries for which neither of these two conditions is fulfilled. **These countries may have a lower level of data protection than the EU.** The [responsible body of the biobank] guarantees that in these cases too, the research partners will be contractually obliged to comply with the EU data protection regulation as far as legally possible. Nevertheless, there is a risk that public or private bodies may access your data, although this would not be permitted under the European data protection regulation. It is also possible that you 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, your biosamples and data can only be passed on if you have expressly agreed to this. You can tick the appropriate box in the consent form.**

d. Evaluation by an Ethics Committee

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

e. Publications

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

8. Do you or the biobank have a financial benefit from the use of your biosamples and 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] to use your data.

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

The biobank uses your biosamples and data 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 be contacted again?

In order to collect further historical data, you may be contacted again at a later time to request additional information and/or biological samples from you. In addition, the renewed contact can be used, for example, to obtain your consent to be linked to medical data from other databases and/or to provide you/your treating physician/study physician/your general practitioner with feedback on results relevant to your health (see point 5 above).

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

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

10. What does your right of withdrawal include?

You can withdraw your consent for using your biological samples and related data at any time without giving reasons and without reprisal. However, the legality of the use of the biosamples and data until 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 accordingly deleting the data, you can also agree that your biosamples or data may be used in an anonymised manner for medical research purposes. Anonymisation means that the identification code is deleted, which could be used to retrieve the person from whom the biosample or data was gained (see above point 7a/b). However, such anonymisation of your biological samples can never completely rule out the possibility that the genetic material might later be assigned to you. As soon as the anonymisation has been carried out, a targeted destruction of such material 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 have?

The legal basis for data processing 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 can request information from [the responsible body of the biobank and the data collecting institution] about the data stored about you within the framework of the legal requirements. 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 data processing and compliance with data protection, 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].

You 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 I 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 [...] at a later date for further questions.

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

Declaration of consent

Patient/proband (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 reprisal.

I agree that my biological samples and related data, 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 my personal data, especially information about my health, takes further personal data from my medical records if necessary, and stores the data in a pseudonymized fashion (i.e. coded);**
- **the biosamples are stored in a pseudonymised fashion by [biobank organisation/ host institution or legal body of the biobank/client]. 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 pseudo-nymised fashion 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 pseudo-nymized biosamples and/or data for research projects in countries outside the EU. This is generally permissible if a decision on adequacy has been made by the European Commission or officially approved data protection clauses are applied.

In addition, I consent to the transfer of my pseudonymized biosamples and/or data to countries outside the EU in cases where no adequacy decision by the European Commission has been issued and no officially approved data protection clauses are applied. 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 patient/proband information (point 3): I would like to restrict the use of my biosamples and data in terms of subject matter or time as follows

.....

I agree that 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 my data with medical data from other databases,
  □ yes □ no

- for the purpose of providing feedback on important health-related results
  □ yes □ no

This feedback should be given by the institution where my biosamples/data was obtained or by the following physician (if desired, please specify):

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

_____

Name of the patient/proband in block letters

_____ _____

Place, date (to be entered by the patient/test person), signature of the patient/test person

I have conducted the clarification interview and obtained the consent of the patient/research participant.

_____

Name of the person providing information in block letters

_____ _____

Place, date, signature of the person providing information