**Template**

**For informed consent concerning the donation, storage, and utilization of biological materials as well as**

**collecting, processing, and usage of (related) data in biobanks**

Recommended by the Permanent Working Party of the German Medical Ethics Committees   
approved by the General Assembly on 09.11.2013

**Patient/study-participant information for individuals who are currently being treated or examined in a clinic/hospital**

*The following Participant Information Sheet template is intended for use by biobanks supporting medical research, i.e. the colleting of human biosamples and related data, which use is not restricted to a specific research project with a clearly defined research purpose. It covers all essential aspects of the information and consent process and should be used as a guidance tool. The template must be adapted to the specific requirements, scope and aim of the respective biobank.* ***In particular, more specific information is to be provided wherever possible.***

*The patient must be informed in an oral consultation by a physician.[[1]](#footnote-1)*

*Text passages in italics are guiding instructions for individual adaptations and should be omitted from the final text handed out to the patient/ participant. The same applies to alterna­tive formulations.*

***[Letterhead (address/contact person) of the institution/department collecting the bio­materials and data, including the administrative office responsible for the data]***

**Information for patients/participants**

Dear patient, dear participant,

You are currently being treated as a patient at the *xy clinic/hospital* or participate in the *yz study*. The clinic/hospital *cooperates with / supports [name of the biobank organisation or body responsible for the biobank] / operates a biobank*. This biobank collects human biologi­cal materials such as blood, urine or tissues linked to selected medical information.

The analysis of human biological materials and data obtained or to be obtained from them has been recognized as an important instrument for current and future medical research. Therefore, we ask our patients/participants – and thus also you – whether you might be will­ing to donate certain biological materials and (related) data for medical research. Please note that your participation is entirely voluntary. If you do not want to participate, you may decline or withdraw your consent at any time without any negative consequences for you.

Below you will find information on the aims and scope of [*name of biobank/ organisation*], their policies and all measures that are being taken to protect your privacy that will enable you to form your own opinion before making a decision.

If any points remain unclear, please ask your attending physician or your study physician before giving your consent. If you have any further questions at a later stage, you may also contact

………………………………………. ................... (fill in a contact/contact person)

**1. Aims and scope of the biobank**

[Name of biobank organisation] supports medical research. Human biological materials and selected data are stored long-term and made accessible for medical research in an effort to improve the prevention, diagnosis and treatment of human diseases. *The scope of the respective biobank is to be described as specifically as possible.*

**2. What type of biomaterials and data are collected?**

*Please note: this paragraph only refers to tissues, blood, and urine. If there is a plan to collect other/additional biomaterials (e.g. liquor, saliva, smears, stool), the text has to be adapted accordingly.*

*For patients:* The biological materials which we would like to store and use for research are tissues and body fluids that have been collected for diagnostic/therapeutic purposes in the course of your present hospital stay, but which are no longer required for such purposes and would, therefore, be destroyed otherwise. *If applicable:* In addition, we would like to obtain and store the following materials [**exact type and quantity of blood/urine/other samples**]

The data collected include information about your person; in particular, medical/health data (*specify additionally collected data, e.g. genetic data, as required*).

*For study participants:* The biological materials collected comprise ..., which are *additionally* taken in the frame of your current study participation. The data collected include selected information about your person: in particular, medical/health data (*specify additionally collected data, e.g. genetic data, as required*).

*If, during future hospital stays or follow-up visits, collection of further biomaterials is planned, they should be described here. The same applies for the collection of data during future hospital stays or follow-up visits.*

**3. How will the biomaterials and data be used?**

*Broad donor consent generally requires a well-defined framework. In particular, broad con­sent should only be sought in cases where the scope of the biobank cannot be restricted to specific diseases, research purposes and/or diagnostic tests. If the research project has a limited duration, the donors should be informed as to what will happen to the materials and data at the end of the intended usage period.*

*Broad consent:* Your donated biomaterials and data will be made available exclusively for medical research purposes. In order to realize the largest possible public benefit they will be used for a wide range of medical research. At present, it is not possible to describe all future medical research objectives. These can either refer to defined disease areas (e.g. cancer, cardiovascular diseases, brain disorders), to diseases that at present are still partially un­known and to genetic disorders. Thus it is possible that your biomaterials and data may also be used for research purposes which, at this stage, are unknown. *If applicable:* Conse­quently, it is also possible that genetic analyses will be performed that might involve sequencing your whole genome. The biomaterials and data are intended to be stored and made available for medical research for an undetermined period of time. *If storage for a limited time is intended, please specify for how long.*

*More restricted consent:* Your donated biomaterials and data will be made available exclu­sively for the investigation of the following diseases/for the following research-areas …. However, the exact research question(s) can often not be specified at this stage. *If applica­ble:* Consequently, it is also possible that genetic analyses will be performed, which might involve sequencing your whole genome. The biomaterials and data are intended to be stored and to be made available for medical research for an undetermined period of time. *If storage for a limited time is intended, please specify for how long.*

*Either:*

You can choose to restrict your consent (e.g. exclusion of certain research areas, exclusion of the transfer of donated materials/data to third parties).

*Or:*

For logistic reasons, the biobank is not able to handle individual consent restrictions (e.g. exclusion of certain research areas, exclusion of the transfer of donated materials/data to third parties). If you are not willing to fully accept the type and duration of use described above, your biomaterials and data will not be used for the biobank.

**4. What are the risks associated with your donation?**

***a. Health risks:***

***(Note for the respective biobank: Delete the case which is not applicable!)***

***Case 1:*** *Only residual material will be used.*

As we intend to use only biomaterials that will be collected in the context of your diagnosis or treatment and that, otherwise, would be destroyed as residual material, the donation does not entail any additional health risk for you.

***Case 2:*** *Additional material will be taken in the frame of an already scheduled intervention.*

For diagnostic or therapeutic reasons we need to take some blood samples from you. On this occasion we would like to take an additional ... ml of blood (corresponding to approximately … table spoons).Taking this sample does not entail any additional health risk for you.

*If applicable: please adapt for sampling of other body material!*

***Case 3:*** *An additional intervention is planned to obtain samples.*

For medical research, we would like to draw ... ml of blood (corresponding to approximately … table spoons). Your willingness to donate blood for the biobank is only associated with the low risks of routine blood sampling. In rare cases, secondary bleeding from the puncture site may occur, or in very rare cases nerve or blood vessel damage may occur that under certain circumstances may persist long-term.

*If applicable: please adapt for sampling of other body material—to the extent that this is permissible!*

***b. Further risks:***

Any collection, storage and transfer of data related to your biomaterials in the context of (medical) research projects entails the risk of breaches of confidentiality (e.g. the possibility of identifying you), particularly regarding your genetic information. These risks cannot be completely excluded and rise with increasing amounts of linked data, particularly when you make further genetic information available on the internet (e.g. for purposes of genealogy). [Name of biobank organisation] will take all appropriate measures according to the current state of technology to protect your privacy and will transfer samples and/or data only to researchers/projects who can demonstrate appropriate data protection and confidentiality safeguards (*see* Item 8: “Who has access to your biomaterials and data?”).

**5. What benefits can you expect from the donation?**

*Either:*

You cannot expect any direct personal advantage or benefit for your health from your dona­tion of biomaterials and data. Investigational/analytical results obtained will exclusively serve medical research purposes. We will not feedback any individual results obtained through the investigation/analysis of biomaterials.

*Or:*

You cannot expect any direct personal advantage or benefit for your health from your dona­tion of biomaterials and data. Results obtained will exclusively serve medical research pur­poses.

Feedback of research results is possible in cases where information concerning your health is significant. This is the case when a (possibly life-threatening) disease can be prevented or a previously undiagnosed health disorder can be treated. Please note that you might be obliged to disclose such information somewhere else (e.g. when applying for insurance). If you do not want to be informed, please deny the possibility of re-contact (see Item 10) by ticking the respective box on the consent form.

**6. What are the benefits for society?**

All current as well as future biomedical research projects aim at enhancing our under-stand­ing of pathogenesis and diagnosis, and - based on this - at developing novel or improved therapeutic approaches/strategies. *If applicable:* General information on the activities of the biobank can be found at … [Internet address/ biobank homepage].

**7. What are the constraints and safeguards for the use of your biomaterials and data?**

**a.** A mandatory pre-requisite for the acquisition and use of your biomaterials and related personal data for research purposes is your written consent. Your consent is voluntary and can be withdrawn at any time (see also Item 11 “What does your right of withdrawal include?”).

**b.** Your biomaterials and/or data will be stored in [biobank] under standardized quality and security conditions (*if applicable:* for an undetermined period of time) and are available for (medical) research purposes on request only. They are protected against unauthorized access according to the current state of technology.

**c*.*** *If applicable:* A mandatory pre-requisite for the use of the biomaterials and data for a specific medical research project is a review by an ethics committee. The ethics committee assesses/evaluates the ethical and legal aspects of the respective research project.

**8. Who has access to your biomaterials and/or data and how are they protected?**

**a.** Any data that directly identify you (name, date of birth, address, etc.) are replaced by a code (pseudonymized, encoded) immediately after they have been obtained. *(If applicable, as it should generally be required:)* Following this, the encoded data set is re-coded again before it is stored. Based on current knowledge, this double encoding/pseudonymization pro­cedure minimizes the possibility that you may be re-identified by unauthorized parties. The bio-materials and/or data will only be made available for research purposes in this form (i.e. double pseudonymized).

**b.** *The following paragraph assumes that the biobank does not hold any identifying data and that such data are held by the institution (clinic/physician) in which they were obtained. Such conditions are preferable, because the personal identifying data are then protected by medi­cal confidentiality and legal access restriction. If any other procedure is planned, this must be clearly stated:*

Data that directly identify you (personal identifying data) remain at the hospital in which the biomaterials and data have been obtained and will be stored separately from the biomaterials and related clinical data. Access to personal identifying data is necessary only in case addi­tional or missing medical data is needed from your medical records, or in case of a need to re-contact you personally if you have agreed to this (see Item 10). In no case will personal identifying data be transferred to scientists and/or other unauthorized third parties, such as insurance companies or employers.

**c.** Based on pre-defined criteria and following a request/application, the double-encoded biomaterials and medical data may be transferred to other universities, research institutes and research companies, including those in foreign countries, for medical research. Under certain circumstances these data may be linked to medical data from other databases, provided that all legal and regulatory requirements are met.

**d.** Biomaterials and/or data that are transferred to third parties may only be used for the research purpose indicated in the application and must not be passed on by the recipient for other purposes. Material that has not been utilized will be returned to the biobank or destroyed.

**e.** Research results for scientific publication will be anonymized, i.e. data will be published only in a form that does not allow re-identification of the donor. *Please note that this rules out publication e.g. of a whole genome sequence without specific individual consent!*

**9. Will there be any financial benefit for you from the use of your biomaterials and/or data?**

You will not receive any remuneration for donating your biomaterials and/or data for medical research purposes. Should such research result in commercially exploitable results, any profits will not be shared with you.

By giving [name of biobank’s legal entity] permission to use your biomaterials and/or data, you also transfer ownership of the biomaterials to [name of biobank’s legal entity]. Further­more, you agree that [name of biobank’s legal entity] uses your data. You retain the right to correct any data that might have been incorrectly stored or processed at any time.

The biobank may charge a reasonable compensation for providing biomaterials and/or data to users.

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

In certain cases it might be useful to contact you again at a later date to ask you for further (follow-up) information and/or for the donation of additional biomaterials. In addition, re-contact would allow obtaining your consent for integration with other data sources or to provide feedback on research results that are significant for your health to you/your attending physician/study physician (*see* Item 5 above).

*(Explain who [biobank or medical institution] will contact whom [patient/participant/attending hospital physician/researcher/general practitioner], and how [in writing/by telephone] .*

If you do not wish to be re-contacted, please indicate this by ticking the respective box on the consent form.

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

You are free to withdraw your consent for the use of your biomaterials and/or data at any time without giving a reason and without any fear of detriment. In case of withdrawal it is up to you to decide whether your biomaterials are to be destroyed and the corresponding data to be deleted, or whether they may be used in an anonymized form (that is, without any link to your person, *see* Item 8e) for further medical research projects. However, as soon as the link between the biomaterials and data and your person has been removed, previously donated biomaterials can no longer be destroyed. In addition, data cannot be removed from already completed studies/scientific analyses. Please note that, even in case of withdrawal, it is not possible to completely rule out that genetic information may be traced to you via other sources.

For withdrawal, please contact: [name, address, and contact data of the contact office/ biobank organisation]

**Consent Form**

*The following template for patient’s/study-participant’s consent represents a guidance tool and is to be adapted to the specific requirements, scope and orientation of the respective biobank. The Consent Form has to be signed by the patient/study-participant in the clinic/medical practice.*

The patient/participant received the patient/participant information sheet from the **[name of biobank organisation]** beforehand and any additional questions were answered.

**Consent**

Patient/Participant: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

(Name, First name)

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

I, hereby, agree that my biomaterials and/or data will be stored in the **[name of biobank organisation]** and can be used for medical research purposes as described in the infor­mation sheet. This may include transfer of double-encoded biomaterials and/or data for research projects involving foreign countries with a lower level of data protection.

I, hereby, transfer ownership of the biomaterials to **[name of biobank organisation].**

I have read the information sheet and have 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 having to fear detriment/.

I agree that I may be re-contacted at a later date (if not agreed, please tick “No”)

- for purposes of obtaining further information/biomaterials, **□ No**

- for the purpose of obtaining consent for integration with other databases, **□ No**

- for the purpose of feedback on research results that are significant for my health **□ No**

This feedback will take place *via* the institution/hospital in which my biomaterials and/or data were obtained or *via* the following physician (if applicable, please indicate)

Name and address of physician: .....................................................................................

**Data Privacy Statement**

**I, hereby, agree that *[provide name of institution (clinic)/location of record]***

**- collects and stores my personal identifying data**

**- collects/extracts additional information on my health from my health records,**

**- and makes the data together with my biomaterials available to [name of biobank organisation] in pseudonymized (that is, encoded) form for medical research projects.**

*If applicable:* **My biomaterials and data may be used for medical research projects for an unlimited period.**

**My biomaterials and data may be transferred in pseudonymized form to universities, research institutions and research companies, possibly also in foreign countries, for medical research purposes.**

**I have been informed that I can withdraw my consent given to [name of biobank organisation] at any time without giving reasons. In case of withdrawal and based on my decision the remaining biomaterials and collected data will either be destroyed/ deleted or anonymized for further use. Data from analyses that have already been completed cannot be removed.**

I have received one copy each of the patient/participant information sheet and the Informed Consent Form. The original remains with the ***[institution (clinic)/location or name*** *of biobank organisation].*

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

Patient’s/Participant’s name (in printed letters):

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

Place, date (to be completed by patient/participant) Signature of the patient/participant

I conducted the patient/study participant consultation and have obtained the patient’s/ participant’s consent.

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

Physician name (in printed letters):

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

Place, date and signature of the physician

1. Planned modification, implementing § 16 of the Declaration of Helsinki: or adequately trained/skilled staff. [↑](#footnote-ref-1)