

Medical Informatics Initiative

Support Structure – Coordination Office of the National Steering Committee



Consent Working Group Patient Consent Form Template

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Version 1.6d

Comprising information and consent forms for patients

Patient information

on the use of patient data [*where applicable*: health insurance data and biosamples (tissues and body fluids)] for medical research purposes

Dear patient,

You are currently receiving medical care for the purpose of diagnosis and/or treatment at [*name of the institution providing healthcare*]. Within the scope of your healthcare/treatment, patient data [*where applicable*: and biosamples (tissues and body fluids), e.g. obtained via blood samples, biopsies or operations/surgical interventions] may be collected. These patient data [*where applicable*: and biosamples] could have significant value for medical research.

Medical research is essential to the continuous improvement of the early diagnosis, treatment and prevention of disease; the insights we may gain from your patient data and biosamples could potentially make an important contribution to these efforts. We therefore request that you consent to make your patient data [*where applicable*: and biosamples] available to us for the purpose of medical research. With your consent, your patient data will be collected in a database operated by [*name of the database owner/operator*]. [*Where applicable*: The biosamples you provide will be long-term stored in a quality-controlled manner in the biobank(s) and/or archives of [*biobank and/or archive owner/operator*]].

Your consent is entirely voluntary. If you do not wish to participate, or if at a later time you wish to withdraw your consent, you will not suffer from any reprisal.

If you do not fully agree with the type and long-term nature of use described below, or if your questions have not all been answered to your satisfaction, then you should not give your consent.

1. Collection, processing and scientific use of your patient data

1.1 What are our goals?

Your patient data are to be made available for medical research. The sole aim of medical research is to improve the diagnosis, treatment and prevention of disease; your patient data will not be used for the development of biological weapons or for any discriminatory research. **Moreover, it is not the purpose of this research to provide you with a diagnosis or to influence your specific medical treatment.**

Your patient data will be used for a wide variety of medical research purposes to the benefit of society as a whole. At this point in time, it is not possible to describe all future medical research topics that might be applicable; these may range from the study of specific disease areas (e.g. cancer/oncology, cardiovascular diseases, brain diseases) to individual diseases and genetic disorders that we may currently be unaware of. It is therefore possible that your patient data will be used for research activities that we at this time cannot anticipate. Against this background, your patient data [*where applicable*: and biosamples] will be **stored for 30 years from the time your consent is given**, unless you withdraw your consent before this period has elapsed. In special cases, data [*where applicable*: and biosamples] may be of significant value to science beyond this period. In these instances, we would consult the corresponding data protection supervisory authority and an independent ethics committee to determine whether further use of your data [*where applicable*: and biosamples] is possible.

Patient data

Patient data comprise all information about your person used during your medical examination(s) and treatment(s). Examples of patient data include, but are not limited to: data from doctor's letters/notes, your health records, and results, findings and data from medical examinations, such as blood pressure measurements or X-ray images; also included are the results of laboratory tests, including tests of genetic material (e.g. for congenital or acquired genetic disorders, including tumours).

1.2 How will your patient data be used for scientific research?

Your patient data can, upon request, be made available to universities, research institutions, and companies conducting medical research. The recipient may only use these data for the predetermined research purpose for which they submitted their request, and may not use them or make them available for other purposes. Your patient data [*where applicable*: and donated biosamples] will be used solely for scientific purposes; they will not be sold. However, [*name of the institution providing healthcare*] may request reasonable cost reimbursement from the respective user for the provision of quality-controlled data.

The use of your patient data [*where applicable*: and biosamples] for a specific research project requires prior review and approval by an independent ethics committee.

Results published in scientific titles/media are entirely **anonymised**, i.e. are provided in a form that does not allow them to be traced back to you. [*where genetic studies are proposed*: This also applies in particular to genetic information. However, it is possible that your genetic data, up to and including your complete genetic material, i.e. entire genome, may be included in specially protected scientific databases that are not accessible to the general public].

Anonymisation

When your data are anonymised, they are altered in a manner that they can no longer be traced back to your person, or only with disproportionate technical effort.

Your patient data [*where applicable*: and data from the analysis of your biosamples] may also be merged with your data from databases of other research partners (e.g. other hospitals, institutions or registers). A prerequisite is that you have also allowed the research partners to support such a merge.

1.3 Who has access to your patient data, and how are they protected?

All data that directly identify your person (name, date of birth, address, etc.) are replaced by a combination of characters (i.e. they are encoded). This internal identifier and your associated patient data [*where applicable*: and biosamples] can no longer be directly traced back to you. The connection between this internal identifier and the data that directly identifies you will be managed by an independent internal body or, in particular where data is combined across multiple institutions, by an independent external trust centre [*refer reader to the website(s) of this/these entity/entities*]. Without the assistance of this body/trust centre, the patient data provided for medical research cannot be attributed to you, or can only be traced back to you with disproportionate technical effort. Before your data [*where applicable*: and biosamples] are transferred to researchers external to the institution providing you with healthcare, the internal identifier will be replaced by a new code (combination of characters).

Encoding

When your patient data are collected, information such as your name and date of birth are also recorded. This information can easily be used to identify your person. Upon encoding, this information is replaced by a combination of characters. This prevents the information from being easily traced back to you. You will only be identified if and when your patient data are to be supplemented by additional information on you or to renew contact with you (see Section 4).

Data that identifies you will never be passed on to researchers or other third parties, in particular to insurance companies or employers, except where explicitly permitted by you or where governed by law.

Your consent also applies to the possible transfer of your patient data [*where applicable*: and biosamples] for the purposes described to recipients in countries within the European Union or the European Economic Area, or in other countries where the European Commission has determined there is an adequate level of data protection. **Transfer of your patient data to countries where an adequate level of data protection has not been established is hereby expressly excluded.**

You can view the studies using your or others' patient data [*where applicable*: and biosamples] at any time at www.medizininformatik-initiative.de/datennutzung. In addition, you can register at this address for an e-mail distribution list to receive information via e-mail of all new studies at least one week before the data are used.

1.4 What risks are associated with the use of your patient data?

Whenever patient data [*where applicable*: and data from the analysis of your biosamples] are collected, stored and transferred within the scope of research projects, there is a residual risk that these data can be traced back to you through additional information, e.g. from the Internet or social media. This is particularly the case if you publish your genetic or other health data, e.g. for genealogical research, on the Internet.

The risk of personal traceability is greater for genetic patient data. Genetic information typically relates to a specific individual, i.e. yourself. Additionally, in some cases, conclusions on genetic characteristics among your relatives could be drawn from your genetic data.

Should, despite comprehensive technical and organisational protection mechanisms, your data be accessed by unauthorised persons and then, despite the absence of your name, be traced back to you, it is no longer possible to rule out discriminatory or other data use of a type potentially harmful to you or your close relatives.

1.5 How do you personally benefit?

Generally, you cannot personally expect any direct health benefit or advantage from the scientific use of your patient data [*where applicable*: and biosamples]. Your consent will have no impact on your current medical treatment. If any commercial benefit is derived from the research, e.g. through the development of new drugs or diagnostic procedures, you will not share in this benefit.

However, it is possible that in individual cases a result of analysis could be of such significant importance to your health that a physician or researcher considers it urgently necessary to contact you. This is in particular the case where there is strong suspicion of a serious, possibly previously undetected disease that could be treated or whose onset could be prevented.

In addition, there may be further results (additional findings) that might be relevant to your health and of which we would wish to inform you. You may decide whether we are permitted to contact you in these situations. Please note that you may be required to disclose health information received through such feedback to other parties (e.g. before taking out health or life insurance) and could suffer disadvantages as a result. Where information from your genetic material is used for medical research, this may include

your genetic predisposition on your part to certain diseases. You can find further information on genetic data at www.vernetzen-forschen-heilen.de/genetische-daten.

Information from your genetic material may also be important for your family members and for family planning. You can reverse your decision in favour of or against us providing such feedback at any time by informing us.

1.6 What are the benefits to society?

Medical/scientific research projects aim to improve our understanding of the cause of diseases and diagnosis and, on this basis, to improve prevention, care and treatment. Further information on our activities can be found at [website address].

[Where applicable]:

2. Transfer and scientific use of health insurance data

Health insurance data

During your treatment [at/by institution providing healthcare] only data that are required in the direct context of the treatment are collected. For many scientific questions, however, these "snapshots" are generally insufficient. In order to obtain a more comprehensive picture of your state of health, we would, for example, like to also use your data from outpatient care. Your health insurer has this information.

We therefore ask for your consent that we may also request your data relating to previous and future contacts with general practitioners and specialist physicians providing outpatient care and, where applicable, relating to further inpatient treatments (hospital stays) and medication prescriptions, and that we may use this data for scientific purposes. In Section 2 of the consent form, you can authorise us to request the relevant data from your health insurer. However, we do not provide the health insurer with any research data that could be traced back to you. You will therefore not suffer any disadvantage through the use of your health insurance data.

End of health insurer data module].

[Where applicable]:

3. Collection, storage and scientific use of biosamples (tissues and body fluids)

3.1 What are biosamples?

Biosamples

Biosamples are tissue specimen and/or body fluids that have been taken from you for diagnosis or treatment and which, after the conclusion of treatment/examination, are no longer needed (residual materials). Biosamples can be blood, urine, stool, saliva, cerebrospinal fluid, or, for example, tissue removed during an operation or biopsy. These residual materials can be useful for medical research and would be stored in biobanks or hospital or research institution archives. [Where applicable: Moreover, you can also donate additional samples (e.g. a limited additional amount of blood) for medical research purposes to be collected when a routine blood sample is being taken or a planned puncture is being performed (see Section 3.2 below).]

3.2 How are your biosamples used scientifically and protected against misuse?

The same rules and principles, as well as the associated goals and risks, apply to your biosamples and the data obtained from them as described above for patient data. Details are given in Sections 1.1 – 1.6 of the patient information. Biosamples may contain your inherited genetic information. In this regard, we draw attention in particular to the risks for genetic data described in Section 1.4. This includes an increased risk of these data being traced back to you.

The intention is to make your biosamples available for a variety of medical research purposes. To this end, they will be stored in a [*name of the biobank or archive owner/operator*] biobank or an institutional archive and may be made available to other research partners upon request.

Research projects using your biosamples may also include analysis of your genetic material, e.g. for congenital or acquired genetic disorders, including tumours. Under certain circumstances, this may also include examination of your entire genetic material (genome).

[*Where applicable*: For research purposes, it can be very useful to extract slightly more biosample when taking a routine blood sample or performing a puncture than is necessary for your treatment. This additional sample will only be collected if you agree to it specifically on the informed consent form. For your protection, there are limits placed on the quantity of additional sample. [According to the instructions of the physician overseeing your treatment, no more than [*locally agreed maximum*] of blood or puncture fluid (approx. [*locally agreed value*] teaspoons) may be taken for research purposes, or in the case of cerebrospinal fluid up to [*locally agreed maximum*] (approx. [*locally agreed value*] teaspoons) [*Either*: within [*locally agreed time period*] *or*: for each sample]. Quantities above these limits require separate, dedicated patient information and consent.]

3.3 Who has ownership of your biosamples?

By providing your consent to the collection, storage and scientific use of your biosamples, ownership of your biosamples is transferred to [*biobank or archive owner/operator*]. Your samples will not be sold, but the owner/operator may request reasonable cost reimbursement from the user for providing quality-controlled biosamples. Transfer of ownership does not affect your right to determine how your personal data are processed. Despite transfer of ownership, you can withdraw your consent to data processing at any time (see Section 6) and request the destruction of your biosamples.

End of biosamples module]

4. Will you be contacted again?

To request additional information [*where applicable*: or biosamples] from you, it may be useful to contact you again at a later date. In addition, renewed contact may be made, for example, for the following purposes:

4.1

To **ask** you, with your consent, for **additional information relevant to scientific questions**, to inform you of new research projects/studies and/or to obtain your consent to combine your patient data with medical information from other databases, or

4.2

to **inform** you of **additional research findings** (see Section 1.5 above).

You can decline the forms of contact described in 4.1 and 4.2 in the declaration of consent ("right not to know").

4.3

Moreover, irrespective of the above, contact can be made in order **to give you feedback via the physician overseeing your treatment or your general practitioner** on analysis results that could be of significant relevance to you personally (see Section 1.5 above).

5. How long is your consent valid?

Your consent to the collection of patient data [*where applicable*: and of biosamples] is valid for **five years** from the date you give consent, unless you withdraw it before this period has elapsed (see below).

This means that during this five year-period [*institution providing healthcare*] may, with prior notice, collect further data [*where applicable: and biosamples*] without you having to sign a new consent form. If you return to [*name of institution providing healthcare*] after five years, we will ask you to give your consent again (renewal of your consent).

Your consent to the processing and use of the data [*where applicable: and biosamples*] collected until now remains valid beyond this period (see Section 1.1).

6. What does your right of withdrawal include?

Your consent is entirely voluntary.

You can withdraw your consent in whole or in part to the further collection and scientific use of your patient data [*where applicable: and biosamples*] at any time without giving reasons and without any reprisal.

Your withdrawal of consent always only applies to the future use of your patient data [*where applicable: and biosamples*]. Data from analyses already performed cannot be subsequently removed.

In case of withdrawal, [*where applicable:*] the biosamples provided by you for research will be destroyed and] your patient data stored on the basis of your consent will be deleted or anonymised, where this is legally permissible. If deletion is not possible or only possible with unreasonable technical effort, your patient data will be anonymised by deleting the identification code assigned to you. However, anonymisation of your patient data cannot entirely exclude the possibility of subsequent tracing of information, in particular genetic information, to you via other sources.

You can also withdraw individual parts of the consent declaration, for example, if you wish to continue to make the patient data available for research, but have no interest in renewed contact for the purposes of subsequent collection of further data or participation in other studies.

If you wish to withdraw your consent, please contact us at:

[Address/tel./fax/e-mail of body/institution that manages consent withdrawal]

7. Further information and rights

The legal basis for processing your personal data is your consent (Article 9 (2) (a) and Article 6 (1) (a) of the EU General Data Protection Regulation).

The data controller (institution(s) responsible for data processing) for your patient data is [*insert name(s) of corresponding institution and contact details*].

The data protection officer at this institution can be contacted at [*give contact details*].

It is possible for you to lodge a complaint with any data protection supervisory authority. The supervisory authority for this institution is [*name of the data protection supervisory authority*].

In addition, you have the right to access your patient data (including, upon request, the provision of a copy of the data free of charge) and, where applicable, to require that these data be rectified, or deleted, or that processing be restricted.

You also have the right to receive your personal data which you have provided in a standardised electronic format or to have it transmitted to another data controller (body) designated by you (right to data portability).

Patient declaration of consent

Consent to the use of patient data [*where applicable*: health insurance data and biosamples (tissues and body fluids)] for medical research purposes

1. Collection, processing and scientific use of my patient data as described in the patient information; this includes

1.1

the processing and use of my patient data for medical research exclusively as described in the patient information, in conjunction with separate management of my name and other directly identifying data (encoding). I can register at <http://www.medizininformatik-initiative.de/datennutzung> for an e-mail distribution list, which will inform me by e-mail in advance of all new studies to be conducted with patient data (see Sections 1.1, 1.2 and 1.3 of patient information).

1.2

the scientific analysis and use of my encoded patient data by third parties, such as other universities/institutions/companies conducting research; this may include transfer to other countries for research projects if European data protection legislation applies in these countries or if the European Commission has confirmed an adequate level of data protection in these countries. I will not share in any commercial benefit gained from research. Prior to transfer to researchers outside the institution providing me with healthcare, the internal identifier (code) will be replaced by a new code (combination of characters).

1.3

the possibility of merging my patient data with data in databases of other research partners. **A prerequisite is that I have also allowed the research partners to support such a merge.**

I consent to the collection, processing, storage and scientific use of my **patient data** as described in Sections 1.1 to 1.3 of the declaration of consent and Section 1 of the patient information.

Yes

No

[*Where applicable*:

2. Transfer and scientific use of my health insurance data

I hereby authorise my health insurer, where requested by [*corresponding institution/body*] to transfer data on outpatient and inpatient medical care I have received, on prescribed medications and aids, as well as information on long-term nursing care provided to [*name of institution providing healthcare*] as described in the patient information, namely

2.1

once only **retrospectively for data of the past 5 calendar years**. I agree to the transfer of my health insurance number to [*corresponding institution/body*] for this purpose

Yes

No

2.2

For data **from the five years following the date of my signature**. I agree to the transfer of my health insurance number to [*corresponding institution/body*] for this purpose

Yes

No

End of health insurer data module.

[*Where applicable*:

3. Collection, storage and scientific use of my biosamples (tissues and body fluids) as described in the patient information; this includes

3.1

the storage and processing of my biosamples at [*biobank or archive owner/operator*] for medical research purposes exclusively as described in the patient information in conjunction with separate management of my name and other directly identifying data (encoding, see Sections 3.1 to 3.3).

3.2

the scientific analysis of my encoded biosamples as well as their transfer and use by third parties, e.g. universities/ institutes/companies that conduct research, for medical research purposes that have been precisely defined and requested; this may also include transfer for research projects in other countries if the European data protection legislation applies in these countries, or where the European Commission has confirmed an adequate level of data protection in these countries. Prior to transfer to researchers outside the institution providing me with healthcare, the internal identifier (code) will be replaced by a new code (combination of characters).

I also agree to the possibility of merging analysis data of my biosamples with analysis data in databases of other research partners. **A prerequisite is that I have also allowed the research partners to support such a merge.**

3.3

I hereby transfer ownership of my biosamples to [*biobank or archive owner/operator*]. Transfer of ownership does not affect my right to determine how my personal data derived from biosamples are processed (see Section 3.3 of patient information).

I consent to the collection, storage and scientific use of my **biosamples** (tissues and body fluids) as described in Section 3.1 to 3.3 of the declaration of consent and Section 3 of the patient information.

Yes

No

[*Where applicable*: My consent also applies to the collection of small additional amount of biosamples during the routine taking of blood samples or performance of punctures, within the limits described in Section 3.2 of the patient information.

Yes

No]

[End of biosample module]

4. Possibility of renewed contact

4.1

I agree that I may be contacted again by [*name of institution providing healthcare*] to provide additional information [*where applicable*: or biosamples] relevant to scientific questions, to be informed of new research/studies and/or to seek my consent to merge my patient data with medical information from other databases (see Section 4.1 of the patient information).

Yes

No

4.2

I agree that I may be contacted again by [name of institution providing healthcare] to be informed of additional research findings (see Section 4.2 of the patient information).

Yes

No

5. Validity period of my consent

My consent to the collection of patient data [*where applicable*: and of biosamples] during care at [name of institution providing healthcare] is valid for a **period of five years**, from my declaration of consent. If I return to [name of institution providing healthcare] after five years, I can renew my consent. The use of data [*where applicable*: and biosamples] already collected remains permissible beyond this period (Section 5 of the patient information).

6. Right of withdrawal

Your consent is entirely **voluntary**.

You may withdraw your consent in whole or in part at any time without giving reasons to [name of institution providing healthcare] without any reprisal.

Upon withdrawal of your consent, [*where applicable*: the biosamples stored for research and] the data stored on the basis of this consent will be [*where applicable*: destroyed, or respectively,] deleted or anonymised, insofar as this is legally permissible. Data from analyses already performed cannot be removed (Section 6 of the patient information).

*I have been informed about the use of my patient data [*where applicable*: health insurance data and biosamples] and the associated risks, and give my consent within the framework described above. I have had sufficient time to properly consider the matter and all my questions have been answered to my satisfaction.*

I have been informed that I will receive a copy of the patient information and a copy of the signed consent form.

Place, date

First and last name of patient
(block capitals)

Signature of patient

I, in person, provided the patient with information and guidance.

First and last name of employee
(block capitals)

Signature of employee