



Patient Information

on the use of patient data, health insurance data and biosamples (tissues and body fluids) for medical research purposes (BROAD CONSENT)

Dear patient,

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

Medical research is essential to the continuous improvement of the early identification, treatment and prevention of disease; the insights we may gain from your patient data and could potentially make an important contribution to these efforts. We therefore request that you consent to make your patient data 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 Heidelberg University Hospital. The biosamples you provide will be long-term stored in a quality-controlled manner in biobank(s) and/or archives of Heidelberg University Hospital and its contractual partners.

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 face any negative consequences.

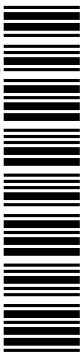
If you do not fully agree with the type and long-term nature of use described below, or if your questions have not all been answered to your satisfaction, then you should not give your consent.

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 identification, 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 activities 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 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 and biosamples may be of significant value to science beyond this period. In these instances, we would consult the corresponding government data protection supervisory authority and an independent ethics committee to determine whether further use of your data and biosamples are 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).

You may have previously received treatment at Heidelberg University Hospital. These treatments may have taken place a very long time ago and may also relate to other diseases. If there were such treatments, patient data were also collected from you at that time, which may also be of considerable value for medical research. In the consent form, you can also allow us to use your previous patient data. This patient data can then also be stored and used scientifically for 30 years from the time of your consent, unless you have revoked it beforehand.

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 and donated biosamples will be used solely for scientific purposes; they will not be sold. However, Heidelberg University Hospital may request reasonable cost reimbursement from the respective user for the provision of quality-controlled data.

The use of your patient data and biosamples for a specific research project is reviewed in advance by an independent ethics committee and requires its positive appraisal.

Results published in scientific media are entirely **anonymised**, i.e. are provided in a form that does not allow them to be traced back to you. 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.

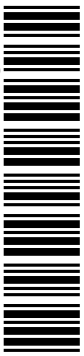
Anonymisation

When your data are anonymised, they are changed so that they can no longer be traced back to your person, or only with disproportionate technical effort.

Your patient data and data from the analysis of your biosamples may also be combined 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 can access your patient data, and how are your data protected?

All data that directly identify your person (name, date of birth, address, etc.) are replaced with a combination of characters (i.e. they are encoded). This internal identifier and your associated patient data 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. For more information, please go to <https://www.klinikum.uni-heidelberg.de/treuhand>. Without the





assistance of this body/trust centre, the patient data provided for medical research cannot be traced back to you, or can only be traced back to you with disproportionate technical effort. Before your data 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 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 and others' patient data 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?

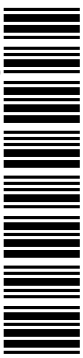
Whenever patient data and data from the analysis of your biosamples are collected, stored and transferred within the scope of research projects, there is a residual risk that these data can be traced back to you through additional information, e.g. from the Internet or social media. This is particularly 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 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 analysis 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 indicate a 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 or against us providing such feedback at any time by informing us.

1.6 What are the benefits to society?

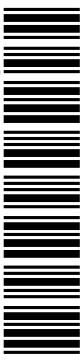
Medical/scientific research projects aim to improve our understanding of the cause of diseases and diagnosis and, on this basis, to improve prevention, care and treatment. Further information on our activities can be found at <https://www.klinikum.uni-heidelberg.de/heidelberg-medic>.

2. Transfer and scientific use of health insurance data

Health insurance data

During your treatment at Heidelberg University Hospital 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.





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. 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).

You may have previously received treatment at Heidelberg University Hospital. These treatments may have taken place a very long time ago and may also relate to other diseases. If there were such treatments, biosamples may have been also collected from you at that time, which may also be of considerable value for medical research. In the consent form, you can also allow us to use your previous biosamples. These biosamples can then also be **stored and used scientifically for 30 years from the time of your consent**, unless you have revoked it beforehand.

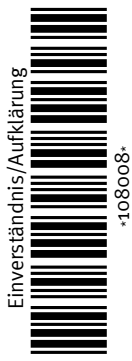
3.2 How are your biosamples used scientifically and protected against misuse?

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 biobank or an institutional archive of Heidelberg University Hospital 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).

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 60 ml of blood or puncture fluid (approximately 12 teaspoons) may be taken for research purposes, or in the case of cerebrospinal fluid up to 10 ml (approximately 2 teaspoons) 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 Heidelberg University Hospital. 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.

4. Will you be contacted again?

To collect additional information 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 medical 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, you may be contacted so that the **physician overseeing your treatment or your general practitioner provides you with feedback** on analysis results that could be of significance to you personally (see Section 1.5 above).

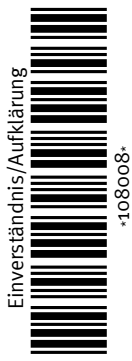
5. How long is your consent valid?

Your consent to the collection of patient data 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 period Heidelberg University Hospital may, with prior notice, collect further data and biosamples without you having to sign a new consent form. If you return to Heidelberg University Hospital after five years, we will ask you to give your consent again (renew your consent).

Your consent to the processing and use of the data and biosamples collected up until now remains valid beyond this period (see Section 1.1).

6. What does your right to withdraw consent 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 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 and biosamples. Data from analyses already performed cannot be subsequently removed.

Where you withdraw your consent, 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:

Universitätsklinikum Heidelberg

Patientenverwaltung – Treuhandstelle

Im Neuenheimer Feld 672

69120 Heidelberg

Tel: +49 6221 56-7066

treuhandstelle@med.uni-heidelberg.de

7. Further information and rights

The lawful 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).

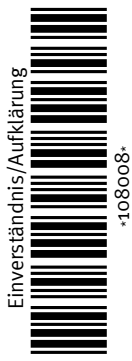
The data controller (institution(s) responsible for data processing) for your patient data is

Universitätsklinikum Heidelberg

Anstalt des öffentlichen Rechts

Im Neuenheimer Feld 672

69120 Heidelberg





The data protection officer at this institution can be contacted at

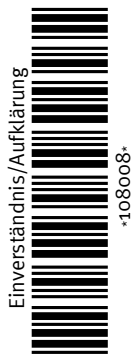
Universitätsklinikum Heidelberg
Die Datenschutzbeauftragte
Im Neuenheimer Feld 672
69120 Heidelberg
Tel: +49 6221 56-7036
E-Mail: Datenschutz@med.uni-heidelberg.de

It is possible for you to lodge a complaint with the corresponding data protection supervisory authority. The supervisory authority for this institution is

Der Landesbeauftragte für den Datenschutz und die Informationsfreiheit Baden-Württemberg
Postfach 10 29 32, 70025 Stuttgart
Königsstraße 10a, 70173 Stuttgart
Tel.: 0711/61 55 41 – 0
Fax: 0711/61 55 41 – 15
E-Mail: poststelle@lfdi.bwl.de
Internet: <http://www.baden-wuerttemberg.datenschutz.de>

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 in a standardised electronic format or to have it transmitted to another data controller (body) designated by you (right to data portability).



Patientenaufkleber



HEIDELBERG
UNIVERSITY
HOSPITAL

Patient Consent Form

Consent to the use of patient data, health insurance data and biosamples (tissues and body fluids) for medical research purposes (BROAD CONSENT)

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 the 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, 0 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 will be replaced by a new combination of characters.

1.3

The possibility of combining 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 consent form and Section 1 of the patient information.



Yes

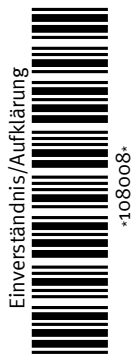
No

I consent to the processing and scientific use of my **patient data, which were collected in the context of previous treatments**, as described in points 1.1 to 1.3 of the consent form and point 1 of the patient information.



Yes

No






2. Transfer and scientific use of my health insurance data

I hereby authorize my health insurer, where requested by Heidelberg University Hospital 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 Heidelberg University Hospital 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 Heidelberg University Hospital 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 Heidelberg University Hospital for this purpose

 Yes No

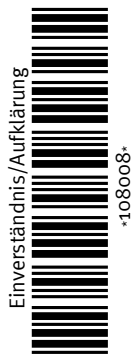
3. Collection, storage and scientific use of my biosamples (tissues and body fluids) as described in the patient information; this includes

3.1

the storage and processing of my biosamples at Heidelberg University Hospital 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 Heidelberg University Hospital. 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

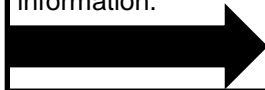
No

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

I consent to the processing and scientific use of my **biosamples, which were collected in the context of previous treatments**, as described in points 3.1 to 3.3 of the consent form and point 3 of the patient information.



Yes

No

4. Possibility of renewed contact

4.1

I agree that I may be contacted again by Heidelberg University Hospital to provide additional information or biosamples relevant to scientific questions, to be informed of new research/studies and/or to seek my consent to combine my patient data with medical information from other databases (see Section 4.1 of the patient information).



Yes

No

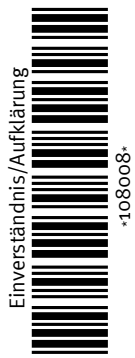
4.2

I agree that I may be contacted again by Heidelberg University Hospital to be informed of additional medical 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 and of biosamples during care at Heidelberg University Hospital is valid for a **period of five years** from my declaration of consent. If I return to Heidelberg University Hospital after five years, I can renew my consent. The use of data and biosamples already collected remains permissible beyond this period (Section 5 of the patient information).

6. Right to withdraw consent

My consent is entirely **voluntary**.

I may withdraw my consent in whole or in part at any time without giving reasons at Heidelberg University Hospital without any negative consequences.

Upon withdrawal of my consent, the biosamples stored for research and the data stored on the basis of this consent will be 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, 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.

Place, date

First and last name of employee
(block capitals)

Signature of employee

