Medical Informatics Initiative

Accompanying structure - coordination office of the national steering committee

Working Group Consent

Sample text patient consent

(as of April 16, 2020)

Version 1.6d

consisting of patient information and consent

patient information

to use patient data [if applicable:

Health insurance data and biomaterials (tissue and

body fluids)] for medical research purposes

Dear Patient,

You are currently being referred to [our/our treating facility name] for diagnosis

treatment or therapy treated by a doctor. As part of your treatment, patient data will be

data [if applicable: and possibly also biomaterials (tissues & body fluids)

obtained, e.g. in the context of blood sampling, biopsies or surgical interventions]. This patient

data [if applicable: and biomaterials] can be important to medical research

Be worth.

Medical research is needed to ensure the early detection, treatment and prevention of

continuously improving diseases; this can include knowledge that we gain from your patient data and

Biomaterials potentially gain a great deal to contribute. We would therefore like to ask you to send us your

Patient data [if applicable: and biomaterials] available for medical research purposes

to provide. Your patient data should be collected in a database that

[holder of the database] is operated. [If applicable: The quality-controlled long-term storage

The biomaterials you provide are stored in biobanks or archives [of the

Sponsor of the biobank(s) or archives].

Your consent is voluntary. If you do not wish to participate or your consent

If you want to revoke it later, you will not suffer any disadvantages as a result.

If you are not comfortable with the type and long-term use described below

fully agree or your queries have not all been answered satisfactorily

have been tested, 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 should be made available for medical research. medical

cal research serves exclusively to identify, treat and prevent diseases

to improve units; Your patient data will not be used for the development of biological weapons or

used discriminatory research goals. Likewise, it is not the purpose of this research to address you

to make a diagnosis or to influence your specific treatment.

Your patient data should be used for many people in the sense of a broad benefit for the general public.

various medical research purposes. At this point you can

all future medical research content is not yet described; these can

relate both to entire disease areas (e.g. cancer, cardiovascular diseases,

diseases of the brain) as well as to individual diseases and diseases that are still partly unknown today

related changes in the genetic material. It is therefore possible that your patient data is used for research

research questions that we cannot foresee at all today. Yours should

Patient data [if applicable: and biomaterials] for 30 years from the date of your consent

stored [if applicable for biomaterials: and stored] if you have not done so beforehand

have revoked. In special cases, data [if applicable: and biomaterials] can also be about

be of considerable importance for science beyond this point in time. In these cases

which we in coordination with the responsible data protection supervisory authorities and an independent

ethics committee to clarify whether further use of your data [if applicable: and bio-

materials] is possible.

patient data

Patient data is all information about you that is collected during your examination and

action. Examples of patient data are: Data from doctor's letters, your medical

layer or findings and data from medical examinations such as blood pressure measurements or

X-ray images; it also includes the results of laboratory tests, including tests

Tests of your genetic material (e.g. for congenital genetic diseases or acquired

genetic changes, including tumors).

1.2 How is your patient data used scientifically?

Universities, research institutes and research-based companies can access your patient data

application for medical research purposes. This data may

Receiver used only for the predetermined and requested research purpose and not for other

other purposes. Your patient data [if applicable: and donated biomate-

riali] are used exclusively for scientific purposes; they will not be sold.

However, [the name of the treating facility] may be responsible for the provision of quality-controlled

collect data from the respective users an appropriate expense allowance.

The admissibility of each individual research project with your patient data [if applicable: and

Biomaterials] is checked in advance by an independent ethics committee and requires their approval

correct rating.

Scientific publications of results are exclusively anonymous, i.e. in

in a form that does not allow any conclusions to be drawn about your person. [If genetic tests are

can be seen: This applies in particular to genetic information. However, it is possible to

taking your genetic data up to the entire genetic material (genome) in specially protected

scientific databases not accessible to the general public.]

anonymization

In the case of anonymization, your data is changed in such a way that it no longer identifies you or only identifies you can be assigned with a disproportionate amount of technical effort.

Your patient data [if applicable: and data from the analysis of your biomaterials] can also be included Your data from databases of other research partners (e.g. other hospitals, institutes or Register) are merged. The prerequisite for this is that you also agree to this use with the relevant research partners have agreed.

1.3 Who has access to your patient data and how is it protected?

All data directly identifying your person (name, date of birth, address, etc.) will be stored replaced by a character combination (encoding). This internal indicator as well as yours with it associated patient data [if applicable: and biomaterials] can then no longer be directly yours be assigned to a person. The connection of this internal indicator with the you directly identifying data is verified by an independent internal body or, in particular, in the case of a Cross-institutional merging of data from an independent external trustee manual [refer to website listing this location(s)]. Without the participation of these The patient data provided for medical research cannot or only with disproportionately high technical effort can be traced back to your person. before one Disclosure of your data [if applicable: and biomaterials] to researchers outside your treat- The setup also involves another replacement of the internal identifier with a new one combination of characters.

coding

When collecting patient data, information such as your name and birth date recorded. Such information can easily be used to identify you personally. This Information is replaced with a combination of characters. In this way a simple che traceability to your person excluded. Your person will be traced back

only if your patient data should be supplemented with additional information about you or

to contact you again (see point 4 below).

Data that identify you personally will be used except where permitted by you or required by law

regulated cases never passed on to researchers or other third parties, especially not to

insurance companies or employers.

Your consent also includes the possibility to have your patient data [if applicable: and biomaterial

lien] for the stated purposes to recipients in states of the European Union or the European

economic area or in other countries for which the European Commission has

measured level of data protection. A transfer to other countries,

in which no adequate level of data protection has been determined is excluded.

At the address www.medizininformatik-initiative.de/datenutilisation you can see at any time which

che studies with your or the patient data [if applicable: and biomaterials] of other patients

be performed. You can also use this address to sign up for an email

Subscribe to a mailing list that will email you about all new studies at least a week before one

Data usage informed.

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

With every collection, storage and transmission of data in the context of research projects

with patient data [if applicable: and data from the analysis of your biomaterials] consists of

the inclusion of further information, e.g. from the Internet or social networks, the restriction

siko a traceability to your person. This is especially the case if you yourself

publish genetic or other health data, e.g. for genealogical research on the Internet.

The risk of traceability in genetic patient data is generally increased. the hereditary

Information from a person is usually clearly related to a person, including you.

In addition, in some cases, your genetic data can also indicate characteristics of your relatives

be closed.

If, despite extensive technical and organizational protective measures, your data should

Jointed hands fall and then, despite the lack of name information, a reference to your person is made.

are asked, a discriminatory or otherwise for you and possibly also close relatives

harmful use of the data cannot be ruled out.

1.5 What are the benefits for you personally?

Personally, you can usually not see any direct advantage or benefit for your health

expect the scientific use of your patient data [if applicable: and biomaterials].

Your consent will therefore have no effect on your current medical treatment. Should-

a commercial benefit from research, e.g. through the development of new drugs or diagnostics

nose procedure, you will not be involved.

In individual cases, however, it is possible that an evaluation result could be so significant for your health

It is important that a doctor or researcher deems it urgently necessary to contact

tet. This is particularly the case if there is an urgent suspicion of a serious

en, heretofore possibly unrecognized disease that can be treated or prevented

could be changed.

In addition, there may be other analysis results that may affect your

are relevant to health (additional findings) and about which we would like to inform you. You can

decide whether we may contact you in this context. Please note that you

health information you may receive through such feedback

must disclose to other bodies (e.g. before taking out health or life insurance).

and could suffer disadvantages as a result. Since medical research may also require information

ions from your genetic material are to be used, this can also have an impact on your genetic predisposition

treatment for certain diseases. For more information on genetic data, see

at www.vernetzen-forschen-heilen.de/genetische-daten.

Information from your genetic material can also have meaning for your family members and the

have family planning. You can make your decision for or against this possibility of withdrawal

change your notification at any time by notifying us.

1.6 What are the benefits for our society?

Medical-scientific research projects aim to improve our understanding

knowledge of the development of the disease and the diagnosis, and on this basis on the new developments

development of improved prevention, care and treatment approaches. Further information

You can find out more about our activities at [Homepage].

[If applicable:

2. Transmission and scientific use of health insurance data

health insurance data

During your treatment [in/on behalf of the treating facility], only data will be collected that

are required in the immediate context of treatment. For many scientific questions

lungs, however, these “snapshots” are usually not enough. To get a fuller picture of your

your health status, we would also like to receive your patient data from the outpatient

use long-term supply. Your health insurance company has this information.

We ask that we also collect data from you, e.g. about previous and subsequent

Doctor contacts with outpatient general practitioners and specialists and, if necessary, further hospital stays

and drug prescriptions and may use them scientifically. Under point 2 in the

declaration of consent, you can authorize us to collect the relevant data from your

request cash register. However, the health insurance companies do not receive any research results from us

Could be assigned to you personally This means that you will not be disadvantaged by using it

of your health insurance data.

end of cash register data module]

[If applicable:

3. Collection, storage and scientific use of biomaterials

(tissues and body fluids)

3.1 What are biomaterials?

biomaterials

Biomaterials are tissue samples and/or body fluids that you provide for diagnosing

Nose position or therapy were taken and after completion of the examinations were not

more are needed (residual materials). This can be e.g. blood, urine, stool, saliva, cerebral

water or tissue that is produced, for example, during an operation or during a biopsy

was taken. These residual materials can be useful for medical research and should

be kept in biobanks or clinic or institute archives. [If applicable: Dar-

In addition, during a routine blood draw or puncture that is planned anyway, you

additional samples (e.g. a limited additional amount of blood) for medical research purposes

donate (see point 3.2 below).]

3.2 How are your biomaterials used scientifically and protected from misuse?

For handling your biomaterials and the data obtained from them as well as for those with them

associated goals and risks, the same rules and principles apply as described above for patient

data have been explained. The details can be found in Sections 1.1 - 1.6 of this patient

duck information. Your genetic material can be contained in biomaterials in the form of genetic data.

In this respect, the risks for genetic data described under 1.4 must be observed in particular.

This also includes an increased risk of traceability of your person based on this data.

Their biomaterials should be available for various medical research purposes. In addition

If these are stored in a biobank or an archive [of the body responsible for the biobank(s) or archive]

preserved and can also be passed on to other research partners upon request.

Genetic studies can also be included in the research projects with your biomaterials.

including examinations of your genetic material, e.g.

diseases or acquired genetic changes, including tumors. This

may also include an examination of your entire genetic material (genome).

[If applicable: For research, it can be very helpful to

tine blood draw or puncture to collect slightly more biomaterial than for support

your treatment requires. This additional withdrawal will only be made if you

but agree in the declaration of consent. In addition, this additional withdrawal is part of your

protection limited. [Either: Within [insert locally tuned interval] or: Per material

al extraction] may not exceed [locally

use correct maximum] Blood or puncture fluid (approx. [locally agreed value] teaspoon

full), with cerebrospinal fluid up to [insert locally agreed maximum] (approx. [locally agreed value]

teaspoon full) can also be taken for research purposes. Withdrawal quantities above this

These limits require separate information and consent.]

3.3 Who Gets Ownership of Your Biomaterials?

With the consent to the collection, storage and scientific use of your biomaterials

at the same time, ownership of the biomaterials is transferred to [the sponsor(s) of the biobanks or

chive] transferred. Your samples will not be sold, but the carrier can be responsible for providing quality

quality-controlled biomaterials from the respective users an appropriate expense allowance

require payment. Your right to determine how your personal data is processed

men, remains unaffected by the transfer of ownership. Despite the transfer of ownership, you can

Revoke your consent to data processing at any time (see point 6) and destroy your

require biomaterials.

end of module biomaterials]

4. Will you be contacted again?

To obtain additional information [if applicable: or biomaterials] from you, it may

make sense to contact you again at a later date. In addition, the

renewed contact can be used, e.g.

4.1

in order, with your consent, to receive additional information relevant to scientific questions

information, to inform you about new research projects/studies and/or to ask for your consent

in linking your patient data with medical information from other data

obtain banks, or

4.2

to inform you about additional medical findings (see point 1.5 above).

You can refuse the contact mentioned in 4.1 and 4.2 in the declaration of consent

(“Right not to know”).

4.3

Irrespective of this, contact can be made to tell you about your doctor

or to give your GP feedback on analysis results that are personal to you

could be of significant importance (see point 1.5 above).

5. How long is your consent valid?

Your consent to the collection of patient data [if applicable: and to obtain bioma-

materials] is valid - if you do not revoke it beforehand (see below) - for a period of five

years from your declaration of consent. This means that during this period [in the/on behalf of the

treating institution] with prior notice from you again data [if applicable:

and biomaterials] may be obtained without you having to re-issue a declaration of consent and

would have to sign. If, after five years, you return [in the/on behalf of the

the institution], we will ask you again for your consent.

Your consent to the processing and use of the data collected so far [if applicable: and

obtained biomaterials] remains effective beyond this period (see point 1.1).

6. What does your right of cancellation include?

Your consent is voluntary!

You can give your consent to further collection and scientific use

Your patient data [if applicable: as well as the biomaterial you have provided

riali] at any time without giving reasons and without any adverse consequences for you

or revoked in part.

A revocation always only refers to the future use of your patient data [if

applicable: and biomaterials]. Data from analyzes that have already been carried out cannot subsequently be transferred

more to be removed.

In the event of a revocation, [if applicable: the data provided by you for the research

provided biomaterials destroyed and] your patient data stored on the basis of this consent

Data will be deleted or anonymized where permitted by law. If not a deletion

or is not possible with reasonable technical effort, your patient data will be anonymized

by deleting the identification code assigned to you. The anonymization of your patients

Duck data can, however, later assign - especially genetic - information

never completely exclude information about you from other sources.

You can also revoke individual parts of the declaration of consent, for example if you

who would like to continue making patient data available for research, but are not interested in one

further contact for the purpose of follow-up surveys or participation in the study.

For a revocation please contact:

[Address/Tel./Fax/Mail: Office/institution receiving the revocation]

7. Other Information and Rights

The legal basis for data processing is your consent (Article 9 paragraph 2 a and Article 6

Paragraph 1 a of the European General Data Protection Regulation).

Responsible for the processing of your patient data is [name(s) of the responsible institution

and insert contact details].

The responsible data protection officer of the responsible institution can be reached at [Contact

specify dates]

You have the opportunity to lodge a complaint with any data protection supervisory authority

the. The competent supervisory authority for your treating facility is [name of competent authority

data protection supervisory authority].

In addition, you have the right to receive information about the patient data concerning you

request, including the provision of a copy free of charge) and, if necessary, their correction

or to request erasure or restriction of processing.

You also have the right to have data provided by you in a standardized electronic format

format or to have it sent to a place specified by you (right to data

ten transferability).

Declaration of Consent - Patient

Consent to the use of patient data, [if applicable:

Health insurance data and biomaterials (tissue 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

identifying data

the processing and use of my patient data for medical research only

as described in the patient information and with separate administration of the name and others

direct

(encoding). At the address www.medizininformatik-

initiative.de/datenutilization I can register for an e-mail distribution list that sends e-mails to all

new studies that are carried out with the patient data before they are carried out

(see points 1.1, 1.2 and 1.3 of the patient information).

1.2

the scientific analysis and use of my encoded patient data by third parties, e.g.

by other universities/institutes/researching companies; this can also be a disclosure for

Research projects abroad include if European data protection law applies in these countries or

the European Commission has confirmed an adequate level of data protection. At any

I will not be involved in any commercial benefit from the research. Before disclosure to researchers

outside of my treatment facility, there is also a further replacement of the internal one

indicator with a new combination of characters.

1.3

the possibility of merging my patient data with data in databases of others

research partners. The prerequisite is that I agree to this use with the relevant for-

research partners also agreed.

I consent to the collection, processing, storage and scientific use of my

patient data like

in points 1.1 to 1.3 of the declaration of consent and point 1 of the

Patient information described.

[If applicable:

□ Yes

□ No

2. Transfer and scientific use of my health insurance data

I hereby authorize my health insurance company to request data about

Medical services used by me in outpatient care and inpatient

other stays, prescribed remedies and aids as well as medicines and information on the area

Nursing at [name of treating facility] as described in patient information

transmit, namely:

2.1

One-time retrospective for the data of the past 5 calendar years. With the necessary

I agree to the transmission of my health insurance number to [responsible office].

□ Yes

□ No

2.2

For data from the date of my signature over a period of 5 years. With the one for it

necessary transmission of my health insurance number. to [responsible body] I agree

□ Yes

□ No

end of cash register data module]

[If applicable:

3. Collection, storage and scientific use of my biomaterials

(Tissues and body fluids) as described in patient information;

this includes

3.1

the storage and processing of my biomaterials in [the sponsor of the biobank(s) or archi-

ve] for medical research purposes only as described in the patient information

and with separate management of the name and other directly identifying data (coding,

see points 3.1 to 3.3).

3.2

the scientific analysis of my encoded biomaterials and their dissemination and use

by third parties, e.g. universities/institutes/researching companies for more precisely defined and

carried medical research purposes; this can also be passed on for research projects in the

Include abroad if European data protection law applies in these countries or the European Com-

mission has confirmed an adequate level of data protection. Before passing it on to researchers

Within my treatment facility, there is also a further replacement of the internal identification

character with a new combination of characters.

I also agree to the possibility of merging analysis data from my biomaterial

included with analysis data in databases of other research partners. The requirement is that I

I have also consented to this use by the relevant research partners.

3.3

I transfer ownership of my biomaterials to [the sponsor(s) of the biobank(s)

or archives]. My right to be informed about the processing of my personal

The right to determine personal data remains unaffected by the transfer of ownership (see

Point 3.3 of the patient information).

I consent to the collection, storage and scientific use of my biomaterials

(Tissues and body fluids), as described in points 3.1 to 3.3 of the declaration of consent and point 3 of the

Patient information described.

□ Yes

□ No

[If applicable: My consent includes taking small additional amounts of

Biomaterial during a routine blood sampling or puncture that takes place anyway in the under point

3.2 of the patient information.

end of module biomaterials]

□ Yes

□ No]

4. Possibility of being contacted again

4.1

I consent to being contacted again by [the name of the treating facility].

may, if necessary, provide additional information relevant to scientific questions [if

applicable: or biomaterials] to inform about new research projects/studies

to be informed and/or for my consent to have my patient data linked to

medical

(see point 4.1 of the

patient information).

obtain information from other databases

□ Yes

□ No

4.2

I consent to being contacted again by [the name of the treating facility].

allowed to ask about additional medical findings

(see point 4.2 of the

patient information).

to be informed

□ Yes

□ No

5. Validity of my consent

My consent to the collection of patient data [if applicable: and to the acquisition of

biomaterials] during stays [at/on behalf of the treating facility] applies for a period of

period of five years from my declaration of consent. If, after five years, I-

who present themselves at the [university hospital], I can give my consent again. the nut

tion of the data I have collected [if applicable: and obtained biomaterials] will remain

This period is permitted (point 5 of the patient information).

6. Right of Withdrawal

My consent is voluntary!

I can revoke my consent at any time without giving reasons to [the name of the

the facility] in full or in part without any disadvantages arising for me.

hen.

Upon revocation, [if applicable: the biomaterials remaining for the research and] the on

Based on this consent data stored [if applicable: destroyed or] deleted or

anonymized where permitted by law. Data from analyzes already carried out

can no longer be removed (point 6 of the patient information).

I have been informed about the use of my patient data [if applicable:, health insurance data and

Biomaterials] and the associated risks and grant in the aforementioned

frame my consent. I had ample time to think it over and all my questions were answered

satisfactorily answered.

I have been informed that I will receive a copy of the patient information sheet and a copy

of the signed declaration of consent will be received.

Place and date

First and last name patient

(block letters)

I conducted the informational interview.

First and last name of employee

(block letters)

Signature patient

Signature of employee