Medical Informatics Initiative

Accompanying structure - coordination office of the national steering committee

Guidelines for the application of the nationally harmonized

Patient information and consent documents

Secondary Use of Patient Data

AG Consent of the Medical Informatics Initiative (MII)

Creator:

AG Consent of the National Steering Committee of the MII of the BMBF

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Background & Purpose

Intended use of patient information documents and

declaration of consent

As part of the medical informatics initiative of the BMBF (MII), all university hospitals in

Germany Data from care and research integrated for uses in both the

direct care as well as for medical research and can be used. In

In a first step, the initiative focuses on the integrated and standardized provision of

Patient data from clinical routine treatment.

As for the cross-site controlled use and provision of patient data

research purposes there is no uniform special legal basis in Germany,

Sample texts for uniform patient information and declaration of consent (in

Furthermore: consent documents) developed. The preparation was carried out in close coordination with the AG

Biobanks of the working group of medical ethics committees (AK EK). The final texts are with the

"Science" and "Health and Social Affairs" working groups of the Conference of Independent

Data protection officers of the federal and state governments as well as ethics committees and others

coordinated with stakeholders.

Regardless of the consent or non-consent of the patient1, other statutory

Permissions (e.g. in the form of a regulation in a state hospital law) for a - possibly

even only local – use of the data or merging of data from different sources

exist, which remain unaffected by this.

The present consent documents are only

patients who are able to consent.

for use by adults and

purpose of this manual

This handout explains the background of the development as well as the typical ones

Framework conditions for using the consent documents. Questions arising in the application

can arise and are not or not sufficiently answered from the documents themselves

can be answered here.

The target group of this handout are the users of the documents as well as committees and people who

Check the processes described here and, if necessary, the documents for consent yourself and

evaluate or be involved in an advisory capacity. This

appointed by state law

Ethics committees, the data protection officers of the institution concerned and those within the framework of the

MII established Use & Access Committees (UAC). In addition, this text can also ask questions

Answered by interested patients and relatives.

are after

Timing of Consent and Requirement for “Broad” Consent

In order to have a representative database free of systematic distortions for many diseases

to obtain consent as early as possible - i.e. before the start of treatment or at the beginning of the

treatment process – necessary. A later date of consent would be the scientific

1 The term "patients" also includes female patients and is used here solely for the sake of better readability.

Significantly limit the significance of patients with an unfavorable course of the disease, who may

can also lead to the inability to give consent or even death,

in the record of

medical informatics initiative would be severely underrepresented.

Because at this necessarily early stage of consent, neither the precise objective

later analyzes based on the patient data nor the extent of the patient data that the

to be subjected to secondary analysis is a specific consent to the

Research on a specific type of disease or even on a specific research project

possible. The purpose of this declaration of consent is therefore broadly formulated.

Other reasons for using a broad consent statement are in a separate one

Document summarized.2

However, as an important limitation, it should be noted that patient data is only available for the

medical research to be made available and medical research to that effect

solely to improve the detection, treatment and prevention of diseases.

In particular, the patient data will not be used for the development of biological weapons or

discriminatory research content used. Likewise, it is not the aim of the research in which

to diagnose patients or influence their specific treatment.

Processes and regulations for the application of the consent documents

As part of the development and coordination of the consent documents with ethics committees and

Regulatory bodies have established processes and mechanisms for their application. have these

the goal of additional risks for the informational self-determination of the affected patients, the

to compensate for the broader purpose and longer storage period. For this

include the following technical, organizational and structural measures:

1. Various information materials are provided to accompany the consent documents

provided. These have the goal that all present and potentially all future

Patients before their consent a comprehensive picture of the meaning and purpose of the MII, as well as the

content and modules of the consent documents. In addition, they should find out about the

possible consequences of their consent and their right to a possible one at any time

be able to inform you about the revocation of consent.

2. On the research projects that will later use the patient data collected as part of the MII

use, must each have a favorable assessment of an independent, according to state law

be submitted to an appointed ethics committee.

3. At the participating university clinics or MII locations, central

Established escrow services that store the identity data in a secure and segregated area

of the affected patients and assigned, internal and non-speaking identifiers

(Coding)3 to protect donor identity and personal rights

manage affected patients.

2 See http://www.medizininformatik-initiative.de/de/mustertext-zur-patienteneinständigung

3 The federal and state data protection authorities involved in the coordination of the consent documents

partly assumes that the separation of identity data implemented in the MII is not subject to pseudonymisation under Art. 4 No. 5 GDPR, since the separated medical data and in particular the biomaterial still contain data Identification potential are included. Against this background, the AG Consent in this handout and in the Consent documents initially on this term. However, the AG Consent of the MII still assumes that the

4. UACs are set up at the participating university clinics or locations of the MII, which bring about the decision on the release of data and/or biomaterials and thereby ensure compliance with all regulations and correct uses.

5. The valid usage regulations are made public.

6. The research projects are published on public websites with information about their funding documented by a central office4 and the participating consortia or locations in order to create transparency for the public.

7. Patients and other interested groups of people have the opportunity to contact an E-Register for a mailing list that provides short-term information about newly registered research projects.

8. Patients who have consented to the use of their data have the right at any time to have their Participation orally or in writing with or without reason and without detriment revoke consequences. The revocation and its implementation are subject to the authority issuing the revocation accepts to document. All institutions, patient data and, if applicable, biomaterials have received, are to be informed about the revocation. If, in exceptional cases, requests are made to the users for exceptions to the obligation to delete in the event of revocation these applications and the decisions on them are transparently available on a central website made.

9. Clearly defined,

ethically and clinically appropriate processes for dealing with additional findings5 established. In addition

the handling of additional findings must be addressed in the project applications.

10. Contracts for the use of patient data and, if applicable, biomaterial on the basis of the submitted

Consent documents are subject to German law. The place of jurisdiction is in Germany.

The following specifications are made specifically for biomaterials:

1. The fate of biomaterials is both in the biobanks of the locations involved in the MII and

also to be documented completely for all users.

2. There is no transfer of ownership of the biomaterials by the biobanks of those involved in the MII

Locations to users instead.

3. Any transmission of biomaterials by users that is not explicitly permitted becomes contractual

excluded.

4. Authorized transfers of biomaterials by users are only possible if they have the same

Terms apply as set forth in the original User Agreement. In addition, everyone must

must be named in the original contract of use.

Process corresponds to a pseudonymization according to Art. 4 No. 5 DSGVO and can be based on a detailed analysis of the

Pseudonymisation term in the GDPR by Roßnagel (Dierks, C., Roßnagel, A., Secondary use of social and

Health data – legal framework. 2019, MWV, Berlin,

https://mwv-open.de/site/books/10.32745/9783954665181/, p. 174.)

4 The URL www.medizininformatik-initiative/datenutilisation is initially reserved for this purpose.

5 The term “additional findings” is used here in accordance with the consent documents. It's with

however, no findings in the sense of a reliable clinical diagnosis are meant.

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5. If consent is revoked, there is a contractual right to destruction in relation to the

affected biomaterial to the respective users.

All technical, organizational and structural measures are defined in a generic

Documented data protection concept, which is coordinated with the data protection supervisory authorities.

The data protection concepts of the locations in the MII are based on this uniform data protection concept

on. The AG Consent of the MII expressly recommends making all data protection concepts public on the web

to make accessible.

Modular consent documents: structure and customization options

Requirement for national standardization of the consent form of the MII

A legally compliant cross-site use of patient data and, if necessary,

Consent-based biomaterials requires semantic at all sites

identical

consent documents.

According to Art. 7 Para. 1 of the EU General Data Protection Regulation (GDPR), the responsible bodies must

be able to demonstrate that the data subjects are involved in the specific processing of their data

have consented. If the data and possibly biomaterials are used across locations

such evidence based on the semantic content of each individual consent document

must obtain, which was presented to one of the affected patients at one of the locations, only

are kept if all consent documents used with regard to data protection law

relevant statements have matching formulations. In the event that the texts of the

Consent documents are not accepted in accordance with the specifications of this handout,

Evidence of equivalence under data protection law must be provided at the respective location and

be documented.

In addition, such a national harmonization also creates greater transparency towards the

patients. They can thus rely on the MII consent documents at all locations

be presented with identical content. Ideally, they already know the content based on the

public relations work of the MII or from a treatment stay at another location. This

The extent to which patients are informed within the framework of the MII must not be caused by unexpected

formulations at one of the locations are subverted.

In order to avoid legal uncertainties resulting from semantic divergence and the patient

to maintain the greatest possible transparency is therefore an exact adoption of the text of the

submitted consent documents are mandatory.

This procedure then also enables a uniform translation of the consent documents in

other languages. Consented and checked translations into various foreign languages as well as into

simple German language are available on the website of the Medical Informatics Initiative6.

Modular construction

Obtaining a large number of declarations of consent and securing the necessary consent

The necessary education as part of routine care represents a major challenge

practical implementation is only possible with good organization and efficient use of resources.

6 see www.medizininformatik-initiative.de

In this respect, patient information and the declaration of consent must, on the one hand, be based on the one location

absolutely necessary

Content and choices are limited. on the other hand

However, the locations in the MII differ in terms of their requirements for content and

choices. For example, locations with a centralized biobank are usually

also want to obtain consent for the use of biomaterials, whereas this is the case for others

Locations without such an infrastructure is not necessary. The consent documents were therefore modularly structured so that each location only gives consent for the locally relevant content and can get choices. In addition, the confrontation of patients with additional Information and consent forms largely avoided. The individual modules are content-wise and formally clearly separated from each other. To later cross-site and interoperable To guarantee data usage, the modules must be fully adopted or left out entirely become. Two modules are marked as compulsory modules in order to ensure a minimum level ensure interoperable data usage. The other modules can be flexibly combined become.

In the Word file with the patient information and informed consent form, all are numbered References to chapters and sub-items as automatically updatable cross-references (with the help of Word field codes) added. In this respect, by updating all field codes in Microsoft Even after removing any modules, Word always automatically creates a version with the correct one references are created.

Currently, the following modules are included in the consent documents in this order:

• Routine data usage (mandatory)

• Retrieval and merging of patient data with patient-related Payer data/health insurance data (optional)

• Use of residual biomaterials and the add-on permitted according to the consent documents samples (optional)

• Permission to be contacted again (mandatory)

The currently agreed set of modules will be supplemented with additional content. Currently the the following modules are planned:

• Permission to contact the family doctor for obtaining additional data and the correspondingly necessary release of the general practitioner from confidentiality;

• Use of those already available in the treating institution from past decades

Patient data and, if applicable, biomaterials stored in biobanks or archives;

• Biomaterials, such as a blood sample, beyond those used in the treatment context

required additional amount of blood allowed in the consent text or one

Removal of tissue that requires another intervention, e.g. puncture. In these cases is

clarification by medical personnel and documentation of this clarification necessary;

• Use of and comparison with population register data.

For patient and test person information including declarations of consent in studies or others

research project

in planning, which the subsequent use of this

Study data allowed in context and according to the rules of the MII. This module should then be used as a text block in

other consent documents can be adopted and in terms of a graded

Declaration of consent to offer the subsequent use of the data as an option.

is an additional module

If there are requirements for further modules, these must also be replaced within the MII by the

AG Consent to be coordinated and harmonized. Accordingly, suggestions can already be included

specific wording suggestions, can be submitted to AG Consent at any time.

Supplementary information offers, forms and variants of the sample texts

The following additional information is in development:

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Information video (approx. 4 min. running time) for patient information and declaration of consent in

German and English, with and without subtitles in the respective language and in variants

with and without modules for biomaterials and cash register data

Information flyer for patient information and declaration of consent

Offer of information on the use of genetic data in research and the possible

Consequences for the affected subjects and patients

The following variants of the sample texts for patient information and declaration of consent are in

Preparation:

• Variants for children and young people and their legal guardians

• Variants in other languages

In addition, a standardized revocation form for optional use is in preparation.

Necessity and limits of local adaptation

The first necessary adjustment is the two optional modules on the biomaterials as well

to check the health insurance data and to decide whether and which of the modules are to be used at the location

should be. Unused optional modules must be completely removed from the documents.

The consent documents contain a number of placeholders that always precede an application

be replaced with specific information. The placeholders are enclosed by square brackets

marked ("[...]"), which are to be deleted after the replacement. The ones to insert instead of the placeholders

Information concerns, on the one hand, necessary specifications regarding the local location and, on the other hand

References to optional modules that are easy to delete when the module is deleted. the latter are

usually introduced with the phrase "if applicable ...". Before using the documents must all

Placeholders in square brackets have to be completely replaced.

For the quantity limitation in the collection of additional biomaterials within the scope of routine

Two mutually exclusive options are available for withdrawals: The total amount

limitation over a time interval or a quantity limitation per material extraction.

The selection of the option and the determination of the specific quantity limit per time interval or

Collection must be coordinated with the local ethics committee.

Further changes to the text of the consent documents are not permitted. The

use

corresponding

Patient information and associated informed consent forms are only permitted if the above

stated rules are observed.

and/or figurative mark

"MII Consent"

the word-

the

on

Presentation/formatting of the documents

The standardization approach primarily refers to the textual content of the documents, not that

Layout. This must meet the usual legibility requirements. Emphasis etc., the one

weighting that deviates from the template or the like should be avoided

become. An electronic presentation, e.g. on mobile devices, is explicitly permitted and desired.

The explicit consent, i.e. the active selection of information must be retained, whereby,

unless an active yes/no decision is technically enforced for each module, rejection

must be specified as a preselection in the electronic image.

consent process

The present consent documents are for use

within the stationary

admission process in university clinics (but also in outpatient clinics, medical practices and others

service providers in the German health care system), but not for this application scenario

limited. In accordance with the World Medical Association Declaration of Helsinki (paragraph 26).

medical advice is not required. This also applies to the additional module "Biomaterial" for as long

no further intervention takes place (e.g. no additional blood sampling or renewed puncture/invasive

intervention). However, specially trained, non-medical personnel are available at the sites to provide information,

including answering any open questions from patients and obtaining consent.

As part of the informational talks, patients should also be made aware of

that information can result from the use of patient data and possibly biomaterials -

in particular in connection with the processing of genetic data – which is also for their

Blood relatives are of great importance. In this respect, the possibility should also be pointed out

to discuss the decision on this consent with close family members.

To secure and document the consent process, it is recommended that consent

in addition to the signature of the patient, also have it signed by the person who

carried out clarification and obtained consent.

The signed consent document can either be archived in paper form or scanned and

then archived electronically in an audit-proof manner. In any case, obtaining an informed must

Consent can be proven. There may be additional requirements for consent from the

State data protection or a state hospital law applicable. These can also

Written form requirement, so that in these cases the destruction of the original document

can lead to legal risks.

The declaration of consent can alternatively be presented in electronic form and (electronically)

to be signed. In this case, too, the obligation to provide evidence must be observed. In addition, the

Complete electronic mapping of the consent process with state law,

specific framework conditions, such as a written form requirement, collide. Next is at

Presentation of all information in electronic form to note that patients also become one

any later point in time still have to be able to verify the conditions under which they

which form of data use you have consented to. For this, the original texts still have to be sent to them

To be available.

For interoperability between sites, it is recommended that the consent status be increased

Each module as well as the document version and the date of consent are collected and structured

be stored electronically. For this purpose, an implementation specification is currently being developed as part of the MII

Developed.

In order to ensure that the patients are voluntarily and informed, they must first be of legal age

and to determine the ability of the affected patients to give consent. A direct coupling of

consent process

administrative and mandatory for the treatment of patients

accounting-relevant processes such as e.g. B. the contractual agreements on inpatient treatment

("Hosting Agreement") is not permitted. In particular, the consent documents must not be part

of the admission contract are presented or suggested to the patient in any way that

the signature would be a requirement for treatment. To achieve this, the

Consent process from the administrative admission process taking into account practicability

and resource availability are decoupled as far as possible.

To ensure that patients are better informed, accompanying multimedia information should also be available in the future

contribute to the consent documents. These are intended to enable patients to

In the run-up to the treatment situation, but at least in the run-up to the consent process, yes

in detail about the purpose, content and consequences of consent within the framework of the MII and about the Right to and possible ways of withdrawing consent. In addition to detailed referenced online materials, short films are also being developed for this purpose, which e.g. B. on screens in Waiting areas or patient rooms can be presented.

Data storage and data use: ethical and data protection aspects

Data protection legal responsibility, data protection concept

A patient's consent to the secondary use of their patient data is generally required obtained separately for each location in the MII. When a patient is in multiple locations consecutively is in treatment, he must consent to the secondary use of his patient data at each location.

The facility/institution at the site that obtains the relevant consent is specific as to designate the responsible body and for the implementation of the following from the consent process steps, including the implementation of revocations. Vice versa must also each individual consent can be revoked individually at the responsible office.

The concrete design of the implementation of routine data secondary use on the basis of harmonized consent documents is in a specific and responsible body to describe a specific data protection concept. The data protection concept must also Requirements for a data protection impact assessment according to Art. 35 EU-DSGVO are sufficient. The creation must be coordinated with the data protection officer of the responsible body. In some cases it can the data protection concept is also checked by the competent supervisory authority. To the to simplify the coordination and testing of the data protection concepts at all locations and To be able to guarantee a uniformly high standard of data protection within the framework of the MII, the Data protection concepts at the locations based on a generic concept that is in preparation which in turn is coordinated with all responsible data protection supervisory authorities.

The data processing itself is in the processing directory according to the General Data Protection Regulation document.

Ethical Advice

In accordance with the World Medical Association's Taipei Declaration (paragraph 19), the

Establishment of a data integration center in the MII and, if necessary, the establishment of one

affiliated biobank received the approval of an independent ethics committee.

For each research project in the context of which data and, if applicable, biomaterials from the locations of the

MII are used, is a positive assessment of the leader of the research project

independent ethics committee and submit it to all relevant sites. a den

professional requirements for doctors, if necessary, sufficient proof of advice from an independent

Ethics committee without a positive evaluation is not sufficient for this.

Recontact and notification of analysis results

The consent documents see a differentiation between analysis results that a medical

Trigger duty of care, and other additional findings. The former refer to the fact that in

In individual cases there is the possibility that an evaluation result for the health of those affected

Patients of such significant importance is that a doctor or researcher is contacted as

deemed urgently necessary. This is particularly the case when there is an urgent suspicion

to a serious, previously undiagnosed disease that is being treated or

the outbreak of which could be prevented. Such a case could arise, for example, if

Image data can be found through additional analysis of an aortic aneurysm. currently is

It is not yet foreseeable how often such cases will already occur in the context of scientific analysis

found data. The contact must always be made by a doctor –

if possible out of the treatment context.

In addition, further analysis results may arise that may only be relevant to the

health of the affected patients are relevant (additional findings). About this may only be based on the additional consent in the recontacting module. Such information can relate, for example, to risk factors for certain diseases.

Release of data use

The decision on the actual release of data and, if applicable, biomaterials for use by Research projects will be submitted by local UACs on the basis of the at each site ethics vote and the detailed description of the data required for the project.

In justified individual cases, the local UAC can issue a supplementary statement from the local Get an ethics committee. If the primary advisory ethics committee recommends that for the Research project additional secondary votes from the ethics committees responsible for the sites are to be obtained, the respective local UAC will only advise the project after approval Evaluation of the local ethics committee.

Data transfer to countries with a lower level of data protection

The transmission is in coordination with the data protection supervisory authorities of the federal and state governments of data to countries where the European Commission has not provided an appropriate level of data protection was determined based on the current consent form admissible.

Validity for data collected in the future and renewed consent

On the basis of the consent documents formulated here, the patient data and, if applicable, Biomaterials of the current treatment case and of future treatment cases of the coming ones 5 years of the same facility for subsequent use can be collected or won. But there is possibility that the patient will re-enter a survey of his or her during this period or thereafter patient data and, if necessary, the collection of biomaterials.

storage of the data

The patient data collected on the basis of the present consent documents can be used for

stored for up to 30 years after the patient gave their most recent consent and

used unless the patient objects in the meantime. This deadline is based on

statutory retention periods for patient data in care, so that by the

Provision as part of the MII no sensitive data is stored at the site longer than this

happens in the supply context anyway.

Retrospective data usage

Patient data from previous treatment cases at the time of consent

used if they are used for the current treatment case. This can lead to

For example, data about previous diagnoses, test results and therapies.

outlook

The AG Consent of the MII will process the submitted consent documents according to the requirements

of the locations and consortia of the MII and add further modules.

As before, this is done in close coordination with representatives of the data protection supervisory authorities and

by ethics committees.