Guide to the Use of Nationally Harmonised
Patient Information and Consent Documents
for the Secondary Use of Patient Data

Consent Working Group of the Medical Informatics Initiative (MII)

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Background and purpose

Intended use of documents for patient information and consent declaration

Within the framework of the Medical Informatics Initiative (MII) of the German Federal Ministry of Education and Research (BMBF), data from healthcare and research are to be made available and used in an integrated manner at all university hospitals in Germany to the benefit of both frontline healthcare and medical research. In a first step, the initiative will focus on the integrated and standardised provision of patient data gained from routine clinical treatment.

Since there is no uniform legal basis in Germany for the controlled use and provision of patient data for research purposes across multiple locations, template documents for uniform patient information and consent declaration (hereinafter: consent documents) have been developed. They were drafted in close cooperation with the Biobank Working Group of the Association of Medical Ethics Committees in Germany (AK EK). The final texts have been agreed with the Science Working Group, and the Health and Social Affairs Working Group, of the Conference of Independent Data Protection Commissioners of the Federal German Government and of the federal states, and with ethics committees and other stakeholders.

Regardless of whether the patient has or has not given consent, other legal mechanisms for granting permissions (e.g. provisions within state-level legislation governing hospitals) may exist for the use of data – possibly only locally – or for the aggregation of data from multiple sources, irrespective of the patient’s consent declaration.

The consent documents are only intended for use by patients who are legally adults and capable of giving such consent.

Purpose of this guide

This guide explains the background to the development of, and the typical conditions and constraints that apply to the use of, consent documents. Questions that may arise during their practical application and that cannot be answered or only insufficiently answered by the documents themselves are addressed here.

The target group for this guide comprises users of the documents, and bodies and persons who review and evaluate the processes described here or the consent documents themselves, or who are involved in an advisory capacity. These comprise medical ethics committees established under state-level legislation, data protection officers of corresponding organisations, and the use and access committees (UACs) established within the scope of the MII. Furthermore, this guide can address questions posed by patients and their relatives.

Timing of consent and need for “broad” consent

To create a truly representative data set for multiple diseases that is free from systematic bias, consent is required as early as possible, i.e. before treatment begins or at the outset of the treatment process. Securing consent at a later point would severely limit the validity of research, since patients with unfavourable disease progression, which might lead to their inability to give consent, possibly even to their death, would be highly underrepresented in the Medical Informatics Initiative's data set.

Since at this necessarily early juncture neither the exact objective of later analyses based on patient data nor the scope of the patient data to be subjected to secondary analysis can be known, it is not possible to specifically consent to research for a certain type of disease or to consent to a concrete research project.
The goal given in the consent declaration is therefore expressed in broad terms. Further reasons for “broad” consent are summarised in a separate, dedicated document.¹

However, as an important constraint, the declaration makes clear that patient data are only made available for medical research, and that this medical research serves exclusively to improve the identification, treatment and prevention of disease. In particular, patient data will not be used for the development of biological weapons or for discriminatory research purposes. Moreover, it is not the aim of the research to arrive at a diagnosis of the consenting patient or to influence their specific treatment.

Processes and policies for the use of consent documents

In the course of developing and agreeing consent documents in cooperation with medical ethics committees and government supervisory authorities, processes and mechanisms have been defined for the application of the consent documents. These processes and mechanisms are designed to address the additional risks to the informational self-determination of consenting patients arising from the broader purpose and longer retention/storage period. They include the following technical, organisational and structural measures:

1. The consent documents are accompanied by various information resources. The aim is to enable all current and potentially all future patients to gain a comprehensive picture of the MII’s mission, as well as of consent document contents and modules, before they give their consent. Furthermore, these materials advise patients on the possible consequences of giving consent and on their right to withdraw consent at any time.

2. Any research projects that subsequently use patient data collected within the scope of the MII must first receive positive assessment (approval) by an independent medical ethics committee established under state-level legislation.

3. A central trust centre will be created at each of the participating university hospitals and MII sites to manage the identity data of the patients and associated internal and non-plain-text identifiers (encoded)² in a secure and separate, dedicated area to protect donor identity and to safeguard patients’ privacy rights.

4. UACs will be established at participating university hospitals and MII sites to decide on the approval of secondary use of data and/or biosamples, ensuring compliance with all policies and correct usage.

5. The applicable standardised use and access rules and policies will be made public.

6. The research projects will be documented, with details of their funding, on the public websites of a central office³, and of the consortia and sites involved, to create transparency for the general public.

¹ see http://www.medizininformatik-initiative.de/de/mustertext-zur-patienteneinwilligung

² In some instances, the federal and state data protection agencies involved in the agreement of the consent documents assume that the segregation of identifying data implemented within the MII does not correspond to pseudonymisation in accordance with Art. 4 No. 5 EU GDPR, since the segregated medical data and, in particular, the biosamples, contain data that could potentially enable identification. Against this background, the MII Consent Working Group has, for the time being, avoided using this term in this guide and in the consent documents. However, the MII Consent Working Group assumes that the segregation process corresponds to pseudonymisation according to Art. 4 No. 5 EU GDPR, and refers in this context to a detailed analysis of the term pseudonymisation in the EU GDPR by Rossnagel (Dierks, C., Rossnagel, A., Sekundärnutzung von Sozial- und Gesundheitsdaten - Rechtliche Rahmenbedingungen. 2019, MWV, Berlin, https://mwv-open.de/site/books/10.32745/9783954665181/, p. 174.)

³ For this purpose, the URL www.medizininformatik-initiative/datennutzung has been reserved.
7. Patients and other stakeholders will be given the opportunity to register with an e-mail distribution list that provides timely information/updates on newly registered research projects.

8. Patients who have consented to the use of their data have the right at any time to withdraw their consent verbally or in writing, with or without giving grounds, and without any adverse consequences. Consent withdrawal and its implementation must be documented by the organisation receiving the consent withdrawal. All institutions that have received patient data and, where applicable, biosamples must be informed of consent withdrawal. If, in exceptional cases, users submit requests for exemption from the obligation to delete data upon consent withdrawal, these requests and the corresponding decisions will be made transparently available on a central website.

9. Clearly defined, ethically and clinically appropriate processes for managing additional findings4 will be established at participating university hospitals and MII sites. In addition, the management of additional findings must be addressed in project applications.

10. Contracts for the use of patient data and, where applicable, biosamples based on the submitted consent documents, are subject to German law. The legal venue shall be in Germany.

The following rules apply specifically to biosamples:

1. The location and use of biosamples must be fully documented both in the biobanks of the sites participating in the MII and by all users.

2. There shall be no transfer of ownership of biosamples from the biobanks of the sites participating in the MII to users.

3. Any transfer of biosamples by users to other parties that is not explicitly permitted shall be contractually excluded.

4. Permissible transfers of biosamples by users shall only be possible where the same conditions apply as set out in the original usage agreement. In addition, all users must be named in the original usage agreement.

5. In the event of consent withdrawal, the patient shall have a contractual right to require all users to destroy the corresponding biosample.

All technical, organisational and structural measures are to be documented in a generic data protection plan, to be agreed with government data protection supervisory authorities. The specific data protection plans of MII sites are based on this generic data protection plan. The MII Consent Working Group expressly recommends making all data protection plans publicly available on the Internet.

**Modular consent documents: structure und customisation options**

**Need for national standardisation of MII consent declaration**

To share patient data and biosamples across multiple sites on the basis of patient consent in a way that ensures legal certainty requires semantically identical consent documents at all locations.

According to Art. 7 (1) of the EU General Data Protection Regulation (GDPR), the data controller must be able to prove that data subjects have consented to the specific form of data processing. In the case of

4 The term "additional findings" is used here in accordance with the consent documents. It does not imply findings in the sense of robust clinic diagnosis.
usage of data and, where applicable, biosamples across multiple sites, such proof, which must relate to the semantic content of the individual consent document presented to the patient at one of the sites, can only be provided if all consent documents have identical wording with regard to the statements relevant to data protection legislation. If the consent documents are not worded in accordance with this guide, each site must ensure and document proof of equivalent compliance with data protection requirements.

In addition, national harmonisation creates greater transparency for patients. Patients can be sure that consent documents with identical content will be presented at all MII sites. Ideally, patients will already be aware of the consent document’s content via the MII’s public relations activities or through treatment at another location. This transparency and informed patient status, required and to be achieved within the scope of the MII, must not be undermined by unexpected wording at one of the sites.

To avoid legal uncertainties resulting from semantic divergence and to ensure the greatest possible transparency for patients, it is therefore imperative that the consent documents presented by the MII are adopted exactly as they are, with their wording fully intact.

This also enables the uniform translation of the consent documents into other languages. Approved and verified translations in various foreign languages as well as in simplified German are available on the Medical Informatics Initiative’s website.

Modular design

Obtaining a large number of consent declarations and ensuring patients are properly informed within the scope of routine healthcare is a major challenge. Implementation in practice is only possible with good organisation and efficient use of resources. Patient information and consent declarations must therefore be limited to the content and options absolutely necessary at any given location. However, MII sites differ in terms of their content and option requirements. Sites with a centralised biobank, for example, will typically want to obtain consent for the use of biosamples, whereas this is not necessary for sites without this kind of infrastructure. The consent documents have therefore been structured in a modular way to allow each site to obtain consent for locally relevant content and options. This also means patients are not confronted with additional information and consent forms. The individual modules are clearly differentiated in terms of content and layout/format. In order to guarantee subsequent data compatibility and seamless data use across multiple locations, each module must be employed in its entirety or omitted completely. Two modules are mandatory, and are indicated as such, in order to guarantee a minimum of data compatibility. The other modules can be combined flexibly.

All numbered references to sections and sub-sections in the Microsoft Word file containing the patient information and consent declaration are automatically updateable (cross-reference) fields. As a result, updating all fields in Microsoft Word automatically creates a version with correct references even after the removal of individual modules.

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

- Use of data from routine healthcare (mandatory)
- Access to and combination of patient data with patient-related data from health insurer or other organisation responsible for settling treatment costs (optional)
- Use of residual biosamples, and of add-on samples as described in consent documents (optional)
- Permission to renew contact with the patient (mandatory)

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5 see www.medizininformatik-initiative.de
The current approved set of modules will be supplemented by further content. The following modules are already in planning:

- Permission to contact the patient's general practitioner to obtain additional data, including relieving the general practitioner from their obligation to patient confidentiality;
- Use of patient data already available at the institution treating the patient from past decades and, where applicable, biosamples stored in biobanks or archives;
- Biosamples, e.g. a blood sample that exceeds the amount required for treatment and exceeds the additional amount permitted by the consent document, or a tissue sample that requires further medical intervention, e.g. puncture. In these cases, the provision of patient information/guidance by medical staff and documentation of such provision is necessary;
- Use of and comparison with data held in local government registers of residents.

An additional module is currently in planning for patient and research-subject information, including consent declaration, for studies or other research projects that would allow the subsequent use of these study data in the context of, and according to the rules of, the MII. This module would then be available as a text block for use in other consent documents. This allows patients to give their consent to participate in the study, regardless of whether they also agree to the broad subsequent use of their data.

If there is a need for further modules, these must also be agreed and harmonised within the MII by the Consent Working Group. Correspondingly, proposals for new modules, preferably with suggested wording, can be submitted to the Consent Work Group at any time.

**Additional information resources, forms and versions of template documents**

The following additional information resources are under development:

- Information video (approx. 4 minutes in duration) for patient information and consent declaration in German and English, with and without subtitles in the respective language, and in versions with and without modules for biosamples and health insurance data
- Information flyer for patient information and consent declaration
- Online information on the use of genetic data in research, and on possible consequences for the research subjects and patients

The following **template document versions** for patient information and consent declaration are being prepared:

- Versions for children and young people and for their legal guardians
- Versions in other languages

In addition, a standardised **consent withdrawal form** for optional use is in preparation.

**Necessity and limits of local customisation**

The first necessary act of customisation consists of reviewing the two optional modules on biosamples and health insurance data, and then deciding whether and which of the two modules should be used at the corresponding site. Unused optional modules must be removed in their entirety from the documents.

The consent documents contain a number of placeholders that must always be replaced by concrete content before use. The placeholders are indicated by square brackets ("[...]") that must be deleted once they have been replaced by concrete content. The replacement content comprises, firstly, necessary details on the local site/facility, and secondly, references to optional modules, which can be simply deleted where the module is omitted. The latter placeholders are usually introduced by the phrase "where
Two mutually exclusive options are available for limiting the amount of additional biosample obtained within the scope of routine sampling: a limit on the total sample quantity over a defined period of time or a limit on quantity per sample taken.

The choice of option, as well as the concrete quantity limit per time period or sample must be agreed with the local medical ethics committee.

Further changes to the text of the consent documents are not permitted. The use of the MII consent word mark or symbol on the corresponding patient information and associated consent declarations is only permitted where the above rules are adhered to.

**Presentation/formatting of documents**

Standardisation applies primarily to the text/content of the documents not the layout. The layout must fulfil typical readability requirements. Highlighting of particular elements, etc., that might imply a weighting, emphasis or similar that differs from the original should be avoided. Electronic presentation, e.g. on mobile devices, is explicitly permitted and desired. However, this form of presentation must safeguard explicit patient consent, i.e. active selection/input by the patient. Where this does not take the form of a technologically enforced yes/no decision for each module, the default setting must be the rejection of consent.

**Consent process**

The current consent documents are intended for use within the scope of the admission process for inpatients at university hospitals (but also in out-patient facilities, doctors’ practices and other service providers in the German healthcare system), but are not limited to this scenario. In accordance with the Helsinki Declaration of the World Medical Association (Section 26), information does not necessarily have to be provided by a qualified physician. This also applies to the additional biosample module, provided no further intervention takes place (e.g. no additional blood sample is taken or further puncture/invasive treatment performed). However, specially trained, non-medical personnel must be deployed at the corresponding sites to provide patient information, including answering any patient questions, and to obtain patient consent.

In the course of informed consent discussions, patients should also be made aware that information may be gained from the use of patient data and possibly from biosamples – especially with regard to processing genetic data – which might be of great importance to their blood relatives. In this respect, the patient should be made aware of the possibility of discussing their consent decision with close family relatives.

In order to safeguard and document the consent process, it is recommended that, in addition to the patient’s signature, the consent document be counter-signed by the person who provided the patient information and obtained patient consent.

The signed consent document can either be archived in hard-copy (paper), or scanned and archived electronically in audit-proof form. In both cases, proof must exist that informed consent has been obtained. Under certain circumstances, state-level legislation governing data protection or hospitals may stipulate additional requirements. These may include the need for consent to be made and archived in written form, leading to legal risks should the original hard-copy document be destroyed.

The consent declaration can alternatively be presented in electronic form and (electronically) signed. In this case, too, the obligation to provide proof must be observed. In addition, a consent declaration process
at is entirely electronic may be in conflict with the requirements of state-level legislation, e.g. the need for consent to be made in written form. Furthermore, when presenting all information electronically, it is important that patients are still able to verify at a later time the conditions under which they gave consent and to what form of data use. To this end, the original texts must remain available to them.

To ensure interoperability/data compatibility across multiple sites, it is recommended that the consent status for each module as well as the document version and the date of consent are collected in a structured way and stored electronically. To this end, implementation guidelines are currently being developed within the scope of the MII.

To ensure that patients are acting entirely voluntarily and are properly informed, it is necessary to first determine that they are legally adults and capable of providing informed consent. It is not permissible to directly link the consent process to administrative and cost invoicing/settlement processes necessary and relevant to the treatment of patients, such as contractual agreements for in-patient treatment ("patient admission contract"). In particular, the consent documents must not form part of the patient admission contract or in any way imply to the patient that signing them is a prerequisite for treatment. To this end, the consent process should, as far as possible, be separate from the administrative patient admission process, taking into account practicality, and the availability of resources.

In the future, multimedia resources will be made available to support consent documents. These will help better inform patients in detail on the purpose, content and consequences of consent within the scope of the MII, and on their right to and possible forms of consent withdrawal. In addition to detailed, referenced online materials, short videos will be developed for this purpose that can be presented on screens in waiting areas or in patient rooms, for example.

**Data storage and data use: ethical and data protection aspects**

**Responsibility under data protection law (data controller), data protection plan**

The consent of a patient to the secondary use of their patient data must always be obtained separately at each site within the MII. If a patient is undergoing treatment at several sites consecutively, they must consent to the secondary use of their patient data for each site. The facility/institution that secures the corresponding consent must be specifically designated as the data controller and is responsible for implementing the steps resulting from the consent process, including implementation of consent withdrawal. By the same token, the patient must withdraw consent for/at each site individually by notifying the corresponding data controller.

The concrete implementation of secondary use of data from routine healthcare on the basis of the harmonised consent documents must be described in a concrete data protection plan, specific to the data controller (facility/institution). The data protection plan must also meet the requirements of a data protection impact assessment pursuant to Art. 35 EU GDPR. The plan must be created in consultation with the data controller’s data protection officer. In individual cases, the data protection plan may also be verified by the corresponding government supervisory authority. In order to simplify coordination and verification of data protection plans at all locations, and to guarantee a uniformly high standard of data protection within the MII, the data protection plans at individual locations are based on a generic plan currently being developed, which is being coordinated and agreed with all corresponding government data protection supervisory authorities.

Data processing itself must be documented in the record of processing activities in accordance with the EU General Data Protection Regulation.
Ethical advice

In accordance with the Taipei Declaration of the World Medical Association (Section 19), the establishment of a data integration centre within the MII and, where applicable, the establishment of a corresponding biobank, requires the approval of an independent medical ethics committee.

For each research project in which data and, where applicable, biosamples from MII sites are used, the head of the research project must secure evaluation and approval from an independent medical ethics committee and present this approval to all relevant sites. It is not sufficient to secure proof of receiving expert advice from an independent medical ethics committee without explicit evaluation and approval, even though this advice may, under certain circumstances, meet the usual professional legal requirements for physicians.

Renewed contact and provision of analysis results

The consent documents differentiate between analysis results that mandate a medical duty of care and further additional findings. The former refer to the fact that in individual cases there is the possibility that an analysis result is of such significance to the health of the patient concerned that a physician or researcher considers it urgently necessary to contact them. This is, in particular, the case where the results urgently suggest the possibility of a serious, possibly undetected disease that could be treated or whose onset could be prevented. Such a case could arise, for example, if additional analysis of image data revealed evidence of an aortic aneurysm. It is not yet possible to predict how often such cases will occur within the scope of scientific analysis of data already used for routine healthcare/diagnosis. Contact must always be made by a qualified physician – wherever possible a physician already providing the patient with healthcare.

Moreover, there may be further analysis results that are only of possible relevance to the health of the patient concerned (additional findings). The patient may only be informed of these findings where corresponding additional consent has been given in the renewed contact module. Such information may, for example, relate to risk factors for certain diseases.

Approval of data use

The decision on requests for the use of data and, where applicable, biosamples in research projects is made at each site providing such data/biosamples by its local UAC, on the basis of the approval already given by the local ethics committee responsible for the requesting organisation (primary ethics committee), and a detailed description of the data required. In justified individual cases, the local UAC may request a supplementary statement from the local ethics committee responsible for the site providing the data (secondary ethics committee). However, if the primary ethics committee recommends a second opinion be sought from the secondary ethics committee, then the local UAC will only discuss and decide the request after the secondary ethics committee has given its approval.

Transfer of data to countries with a lower level of data protection

In agreement with the federal and state data protection supervisory authorities, the transfer of data to countries for which the European Commission has not determined an adequate level of data protection is not permitted on the basis of the current consent form.
Validity for data collected in the future and renewed consent

On the basis of the current consent documents, patient data and, where applicable, biosamples may be collected for subsequent use within the context of the current patient treatment case and of future treatment cases over the next five years at the same facility. It is possible, however, that the patient may renew their consent during this period or thereafter to the collection of their patient data and, where applicable, biosamples.

Data storage

Patient data collected on the basis of the current consent documents can be stored and used for up to 30 years after the most recent consent declaration on the part of the corresponding patient, provided the patient does not withdraw their consent. This period is based on the legally defined retention periods for patient data in the healthcare sector, ensuring no sensitive data is stored at the site any longer than is the case in the context of routine healthcare.

Retrospective use of data

Patient data from treatment cases prior to the time of the consent declaration may be used if these data are used for the current treatment case. For example, this might be data on previous diagnoses, test results and treatments.

Outlook

The MII Consent Working Group will further develop the current consent documents with utmost care and according to the requirements of MII sites and consortia, and will add further modules. As previously, this will be performed in close cooperation and agreement with representatives of government data protection supervisory authorities and medical ethics committees.