UNIVERSITÄTS KLINIKUM FREIBURG
Verwaltung des Klinikums
Stabsstelle Rechtsangelegenheiten

Provision of information before treatment measures – Information Sheet –

The obligations to provide information and the requirements for consent to a treatment measure are set out in the German Civil Code (BGB):

Section 630e BGB Obligations to provide information (excerpt)

(1) The treating party is obliged to inform the patient of all and any circumstances which are relevant to consent. This includes, in particular, the nature, extent, implementation, anticipated consequences and risks involved in the measure, as well as its necessity, urgency, suitability and prospects for success with regard to the diagnosis or the therapy. Alternatives to the measure must be referred to in the information if severally equally medically indicated and customary methods may lead to significantly different strains, risks or chances of recovery.

(2) The information must

1. be provided orally by the treating person or by a person with the requisite training to perform the measure; additionally, documents may also be referred to which the patient must receive in written form

2. be in good time so that the patient can make his/her decision on consent in a well-considered manner,

3. be understandable for the patient.

The patient must be provided with duplicates of documents which he/she has signed in connection with the information or consent.

(3) The patient does not need to be provided with information where this can exceptionally be dispensed with due to particular circumstances, in particular if the measure cannot be delayed or the patient has explicitly waived being provided with the information.

Section 630d BGB Consent (excerpt)

(1) Prior to implementing medical treatment, in particular a procedure affecting the body or health, the treating party is obliged to obtain the patient's consent. If the patient is unable to provide consent, consent must be obtained from a party entitled to give such consent …If consent to a measure which cannot be delayed cannot be obtained in good time, it may be performed without consent if it is in line with the implicit will of the patient.

(2) The effectiveness of the consent is contingent on the patient or … the party entitled to give consent having been informed … prior to giving consent.

(3) Consent may be revoked at any time, without stating reasons, and without complying with a specific format.

A. Purpose of the information

The patient must know what is to be done to him/her medically and by what means, and what risks and consequences are involved. The patient may not give legally effective consent to a medical measure until after effective provision of information. Most medical treatment measures are a "bodily injury" which, however, is justified and cannot be punished if the patient was informed beforehand, if s/he gave his/her consent to the measure being performed and if the measure is performed lege artis.

B. Modalities and documentation of the informed consent consultation

Information must be provided on "all essential circumstances for consent".

The information must **always be provided orally**. For the purpose of proving, even years afterwards, what exactly was discussed during the informed consent consultation, every **informed consent consultation must be documented**. To this end, the contents of the consultation must be documented in the patient's file together with the patient's declaration of consent. The Board of Directors of the University Medical Center has decided that, whenever a published template of a patient informed consent form on a treatment measure is available, it must be used! If there is no published template of a patient informed consent form for a procedure, but the measure involves some risks for the patient, the clinic shall prepare such an information and consent form itself and coordinate it with the Legal Department.

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If an informed consent consultation is documented using an informed consent form, it should be evident that the parties did indeed “work” with the form. Underlinings, exclamation marks and additional annotations should be used to be able to refute any subsequent accusation that there was no discussion at all with the patient and that, in particular, the risks involved with the treatment measure were not pointed out to him/her. An informed consent form should be gone through line by line by the respective physician together with the patient.

The patient must be informed if there are alternatives to the planned treatment measure which are also medically indicated and scientifically recognized. The alternatives must be recorded in writing in the informed consent form.

At the end of the informed consent consultation, the informing physician signs and adds his/her name stamp. The patient signs too, thereby giving her/his consent to the implementation of the treatment measure.

The patient must be given a copy of the completed informed consent form. Ideally, the act of providing this copy should be documented in the patient’s file or confirmed by the patient by a further signature on the original informed consent form which remains at the clinic.

C. Provision of information in good time

The information must be provided in good time so that the patient may consider without time pressure whether s/he actually wishes to have the treatment measure performed despite the cited risks.

There is no precise time deadline with respect to how much time must elapse between the provision of information and the performance of the measure. For “major” (more serious) procedures, the patient should be informed no later than the day before the planned procedure, for “minor” (i.e. less serious) procedures, the information may be provided on the same day. The respective medical society shall determine which procedures are “major” and which are “minor”.

It is better to give the patient more, rather than less, time for reflection.

As a general rule, an informed consent consultation with the patient’s consent has no “expiry date”. If, however, several weeks or even months have elapsed between the informed consent consultation and the implementation of the measure, renewed checks must be carried out before the measure is actually performed to verify that there has been no change in the patient’s health. If it has changed, this may mean that the consent based on the previous informed consent consultation may no longer be valid for the upcoming procedure. In this case, a new informed consent consultation must take place.

In an emergency, a treatment measure may be performed without prior information and without the patient’s consent.

D. Who may provide information?

The treating physicians with “the requisite training to perform the measure”. Non-specialist physicians may also provide information, but they must be physicians who are licensed in Germany. Before physicians carry out an informed consent consultation themselves, they should attend several of the clinic’s informed consent consultations carried out by an experienced physician in order to familiarize themselves with the respective modalities of informed consent consultations for treatment measures typically performed at the clinic. Ideally, s/he should also assist with the clinic’s various procedures and treatment measures so that s/he is familiar with the various measures from his/her own experience. This will facilitate the provision of better answers to questions from patients.

Note: If a practitioner wishes to perform a treatment measure without having previously conducted the informed consent consultation with the patient himself or herself, then the practitioner is obliged to check the patient’s file before performing the measure to see whether the informed consent consultation has taken place and whether the patient has actually given his/her consent in writing. Otherwise there is a risk that the practitioner performs a measure even though the patient has not given his/her consent to it.

E. The recipient of information

As a general rule, information is provided to the patient. After all, s/he is the one who has to give his/her consent.

In the case of minors, both parents or persons entitled to the custody must be informed before “major” (more serious) measures are performed so that both may give their consent. In the case of “more minor” (non-serious) treatment measures, it shall be assumed that the person entitled to the custody accompanying the minor was authorized by the person entitled to the custody who is not present. Minors aged 14 years and older may be capable of giving their consent. In this case, they should also be informed and give their written consent. Note, however, that the consent of the parents or persons entitled to the custody is required in parallel!

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In the case of incapacitated adult patients, the holder of a power of attorney or the guardian appointed by the Adult Guardianship Court must be informed and must give his or her consent.

As the patient can only give his/her effective consent if s/he has understood the information provided , the consultation must be conducted in such a way that it is understood by the respective patients. Some patients will already be familiar with the treatment measure and will therefore have fewer queries, for some patients more time will have to be spent to describe the modalities of the measure and the risks in a way that they can understand.

If the patient does not speak German, a sworn interpreter must be called in if possible for the informed consent consultation in accordance with a resolution by the Board of Directors if the informing physician does not happen to speak the patient's language! It must be ensured that the patient understands the information provided in order for him/her to be able to give his/her effective consent. The interpreter must co-sign the informed consent form. Many clinics now offer the possibility to call in interpreters for various languages within a few moments via video. Many published informed consent forms are available in two languages so that, if possible, an informed consent form that can also be read by the patient can be used. However, since the patient file is administered in German, any additions to the informed consent form must also be made in German at least.

The patient may choose to waive the informed consent consultation. Such a waiver should be expressed to two clinic employees if possible. The physician documents the waiver in the patient's file and the other clinic employee, acting as a witness, also confirms the waiver in the file.

F. Queries

This overview has been kept as brief as possible and is therefore incomplete. More in-depth comments on the provision of information can be found e.g. here:

State Medical Chamber of Baden-Württemberg: „Die Aufklärungs- und Informationspflichten des Arztes“ (“The Physician's Obligations in terms of Providing Information for the Patient”) (https://roxtra.uniklinik-freiburg.de/Roxtra/doc/showfile.aspx?fileid=20007)

For clinic-specific or patient-specific queries please contact the Legal Department (Tel. 20480), so that your individual questions can be clarified and answered!