Letter head/Stamp of the treating hospital

English version as requested by clinicaltrials.gov, for presentation at clinicaltrials.gov only

Informed consent form for participation in the clinical study

Qualitative Study on Pain Registration through Innovative Health Technology (QualiPain)

Sponsor of the study
University Hospital Schleswig-Holstein, Campus Lübeck
Coordinating Investigator: Prof. Dr. med. Dirk Rades

Patient: Full name: _____

Date of birth: _____

Investigator: Full name: _____

- The above-mentioned physician infomed me within a personal discussion complete – orally and in written – about the nature, extent and meaning of this study. This included the aim of the study, duration, requirements and possible side effects, my rights and responsibilities, and the voluntariness of participation. I have received and read the patient information form and the informed consent form.

- I had sufficient time to ask questions and to make my decision. My questions were anwered satisfyingly.

- I am aware, that I may withdraw my consent to participate in this study at any time without giving any reasons, without any adverse effects arising on my medical care.

Additionally to the written information the following topics have been discussed:

_____

_____

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I am aware, that this trial primarily serves to expand scientific knowledge in this field and that it may not necessarily result in any personal benefit for me.

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Data protection:

I am aware that in this clinical study personal data, in particular medical findings on me are to be recorded, stored and evaluated in this clinical trial. The data on my health will be used in accordance with legal provisions and will require the following voluntary declaration of informed consent before participation in the clinical trial, i.e., without the following consent, I cannot take part in the clinical trial.

1. I declare my consent that in the course of this clinical study, personal data, in particular details of my health being obtained and recorded in paper form and on electronic storage devices. I consent to the collection, processing and storage of my data as well as the transfer within the scope of the study.
2. Furthermore, I declare my consent to authorized agents of the sponsor bound by a duty of confidentiality, as well as to the competent supervisory regulatory authorities, may have access to my personal data which is in the possession of the study doctor, in particular my health data, as far as this is necessary to verify that the study is being conducted properly. For this procedure, I release the investigator from his/her duty of medical confidentiality.
3. I agree to the condition that my data will be stored for at least 10 years after the end of the trial, or the termination of my participation therein, as stipulated by guidelines for the conduct of clinical trials.
4. I understood, that my consent is revocable and that I therewith may stipulate the deletion of the collected data, as long as no legal documentation- or report obligations are opposed to it.
5. In addition, I have the right to view my stored personal data and have it corrected or deleted. I also have the right to complain to the responsible data protection supervisory authority if I believe that the processing of personal data concerning me violates the existing data protection law.
6. I have the right to receive my personal data that I have provided to the person responsible for the clinical trial. I can use this to request that this data be transmitted either to me or, as far as technically possible, to another agency I have named.
7. I have the right to object to concrete decisions or measures to process my personal data at any time. In general, such processing afterwards does no longer takes place.

The responsible contact person with contact details can be found in the enclosed patient information.

One copy of the information to the stuy (patienten information) and one copy of the informed consent including the data protection to the study have been handed over to me.

I had the opportunity and sufficient time to ask questions. These have been answered satisfactorily and complete and I accept them. I have been given sufficient time to make my decision.

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I herewith declare that I voluntarily consent to participate in the above-named clinical trial.

Name of patient in block capitals

Name of the patient	**Date**	**Signature**

I conducted the informed consent discussion and obtained the patient's consent.

Name of the investigator in block capitals

Name of the investigator	**Date**	**Signature**

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