Patient Information (Parents)

Dear parents,

we would like to include your child in a clinical trial, you will find the details on the following pages. Please read them carefully. If you have any questions please do not hesitate to ask the doctor in charge.

Information about the clinical trial which is named:

Evaluation of the diagnostic accuracy of a Clinical Decision-Support System (CDSS) to support recognition of SIRS and Sepsis in paediatric intensive care patients in comparison to medical specialists.

Your child was or will be admitted on the paediatric intensive care unit (PICU) at Medizinische Hochschule Hannover. Due to neccessary monitoring and therapy we will gather laboratory results and vital signs continueally.

During the clinical trial these laboratory and monitoring details will be analyzed with regard to a pronounced, generalized inflammatory reaction (Systemic inflammatory response syndrome (SIRS)) using the support of a computer-based system. The objective is to support the doctors in early recognition of SIRS.

The recognition of SIRS on a PICU is a complex task that is quite suitable for a Clinical Decision-Support System. SIRS is caused by different reasons, for example surgery, injurys or infection. It is a typical occurence at PICU-patients and puts the patient under additional strain independent from the original reason for admittance. For diagnosing SIRS in paediatric patients correctly we have to find abnormalities in different vital signs and laboratory results which have age related reference values, making it an advanced task.

The development and clinical trial of a CDSS for SIRS in paediatric patients is the result of a cooperation between the Department of Paediatric Cardiology and Intensive Care Medicine of Medizinische Hochschule Hannover and the Peter L. Reichertz Institut für

Medizinsche Informatik der Technischen Universität Braunschweig und der Medizinischen Hochschule Hannover (PLRI).

Are there any risks by taking part in the clinical trial?

The CDSS will only analyze data that is taken and saved during your child's admittance on the PICU anyway. There won't be any additional blood tests, monitoring or examinations. These standardized raised data will be saved in a pseudonymized way that ensures the patient's privacy.

What happens if I don't agree to take part in the clinical trial?

The whole team will respect your decision if you do not want your child to take part in the clinical trial. This will not be evaluated or have any negative effect on your child's treatment. You can also revoke your agreement anytime.

Privacy Policy

The data raised and saved for the trial are pseudonymized and it is impossible to reconnect them to an individual. The data will be saved for 10 years and deleted afterwards. The issues of the Bundesdatenschutzgesetz are considered in every respect.

I received the information and consent to the clinical trial mentioned above.

☐Yes ☐No

_____

(Date and signature of the parent/legal guardian)

_____

(Date and signature of the medical doctor)

Patient Information (Patient)

Dear patient,

we would like to include you in a clinical trial, you will find the details on the following pages. Please read them carefully. If you have any questions please do not hesitate to ask the doctor in charge.

Information about the clinical trial which is named:

Evaluation of the diagnostic accuracy of a Clinical Decision-Support System (CDSS) to support recognition of SIRS and Sepsis in paediatric intensive care patients in comparison to medical specialists.

You were or will be admitted on the paediatric intensive care unit (PICU) at Medizinische Hochschule Hannover. To treat you best we will monitor your vital signs as heartbeat, blood pressure and respiratory rate and take blood tests to monitor your white blood count and other inflammatory parameters. The results will be saved.

We know about the occurence of extreme inflammatory reactions in paediatric patients. These can be cause by several reasons as surgery, injury or infection. We can measure these by changes in your vital signs, temperature or white blood count.
With a clinical trial something new is tested, for example some treatment. For this clinical trial your monitoring or vital sign data will be analyzed by a computer programme to support your doctors to detect changes that might be caused by an inflammatory reaction as soon as possible. The sooner we are aware we can adjust your treatment.

Are there any risks by taking part in the clinical trial?
The CDSS will only analyze data that is taken and saved during your admittance on the PICU anyway. There won't be any additional blood tests, monitoring or examinations. These standardized raised data will be saved in a pseudonymized way that ensures the patient's privacy.

What happens if I don't agree to take part in the clinical trial?

The whole team will respect your decision if you do not want to take part in the clinical trial. This will not be evaluated or have any negative effect on your treatment. You can also revoke your agreement anytime.

Privacy Policy

The data raised and saved for the trial are pseudonymized and it is impossible to reconnect them to an individual. The data will be saved for 10 years and deleted afterwards. The issues of the Bundesdatenschutzgesetz are considered in every respect.

I received the information and consent to the clinical trial mentioned above.

☐Yes ☐No

_____

(Date and signature of the patient)

_____

(Date and signature of the medical doctor)