W/o



## **Declaration of Consent by Parents**

on the scientific study

## Identifying the Causes of Rare Diseases using Genome-Wide Sequencing

	;			······································
and	······································	DOB		,
agree, that				
our child	,	DOB		
is participating in the scientific study "Identifyi wide sequencing".	ing the ca	auses of ra	are disease	s using genome
We were informed about the study in a persor		•	•	
We declare that we have read the study inforr about it have been adequately answered.	mation for	parents a	nd that all c	our questions
If applicable: Our child was diagnosed with the	e following	g rare dise	ase:	
	<del></del>			

We consent that during the care or the treatment of our child, the team of the above-mentioned scientific study may collect information about our child's state of health or may use the already existing medical data of our child as well as, if applicable, data on the course and treatment of the disease (so-called "patient data" as described in the study information). We also consent that this data is recorded, processed and stored in pseudonymised (i.e. encrypted) form.

We consent to the collection and use of pseudonymised (i.e. encrypted) bio-samples from our child, in particular for genetic analyses, which may include the analysis of the entire genetic material - i.e. the genome - as described in the study information. We also consent to the collection and processing of blood samples from our child up to a maximum total volume of 25 ml per year for further laboratory analyses.

Furthermore, we consent to the scientific use of other biosamples from our child, such as tissue samples and/or bodily fluids, which were taken for diagnostic purposes and/or in context of the treatment of our child and are no longer needed afterwards (so-called residual materials), as part of this study.



	Fingernail sample
	Urine sample (spontaneous urine)
	24-hour urine sample
	Saliva
	Skin biopsy (tissue sample from the skin only for children/adolescents of whom a skin sample is taken anyway as part of the medical diagnosis or treatment, no
	additional sample is taken)
	Muscle tissue (only if a muscle sample is taken anyway as part of the medical diagnosis or treatment, no additional sample is taken)
	Cerebrospinal fluid (in children/adolescents only as an additional sample up to a maximum of 5 ml during a routine puncture that is being performed anyway)
	wnership and all rights of use of our child's biosamples to the Klinikum rechts der chnical University of Munich.
	ion of medically relevant results of data analysis from the study "Identifying the re diseases using genome-wide sequencing".
I wish:	
	med of any clues/hints/indications about the possible cause of our child's rare disease that ge from the study
and/or	
which an e	med of additional findings, that put <b>us or our child</b> at very high risk for any disease for effective therapy, useful preventive measures or examinations for early detection of disease ion are available.
The information	on is to be sent to me and/or the following physician:
name:	first name:
address:	
□ not to be in	nformed of analysis results from this study that are relevant for us or our child.
Recontacting	
for example, t	be contacted again by the physicians of this study. Such contact/contacting may be initiated, to discuss additional aspects of our or our child's medical history and/or to request further biospecimens from us or our child.

Furthermore, we consent to the collection and analysis of the following additional biosamples

from our child (please mark with a cross in the list below):

no □

yes □



We agree that **pseudonymised** (i.e. encrypted) patient data and biosamples of our child may also be passed on to departments and research groups of the Klinikum rechts der Isar cooperating in this study and to the genetic research laboratory at Helmholtz Zentrum München for scientific investigation. The results of these analyses and the above-mentioned data will be stored, processed, and analysed on **servers at the Klinikum rechts der Isar of the Technical University of Munich**.

In addition, we can decide whether the double-pseudonymised (i.e. encrypted) data and biosamples of our child may be passed on **beyond this study** for scientific purposes to other researchers/research institutions within and possibly also outside the European Union (EU). It should be noted that transfer to recipients in countries outside the EU is only permitted if one of the following conditions is fulfilled:

- The European Commission has determined an adequate level of data protection in the respective country, or (if this has not been done)
- The Klinikum rechts der Isar signs contractual data protection agreements with its research partners that have been decided or approved by the European Commission or the competent supervisory authority.

Research partners/institutions outside the Klinikum rechts der Isar of the Technical University of Munich will, of course, not given access to medical reports of our child.

We consent that our child's pseudonymised data and biosamples may be shared beyond the scope of this study, both in the EU and outside the EU, under the conditions stated.					
yes □	no 🗆				

Any publication of the results of the study "Identifying the causes of rare diseases using genome-wide sequencing" will only be made in a way that does not allow any direct reference to our child.

We agree that our child's patient data and, if applicable, biosamples will be stored from the time of our consent until our child reaches the age of 18 years (plus one year), unless we or our child revoke our consent before that time.

We consent to our child being contacted again when it reaches the age of 18 years, to be informed again about the study participation and to give a declaration of consent on its own responsibility for the further use of patient data and any biosamples that may still be available. If our child can no longer be reached for its own consent when he/she reaches the age of 18 years (and in the following year), the period of use as consented here will expire. After the period of use expires, our child's biosamples will be destroyed and the patient data will be deleted. If deletion is not possible or not possible with acceptable technical effort, the patient data will be anonymised by deleting the identification code assigned to them.

Our consent to the acquisition of data and the collection of biosamples during our child's presentations/visits is initially <u>valid for a period of five years from the signing of this declaration of consent</u>. If our child presents again at Klinikum rechts der lsar or to the physician in charge after five years, we – or our child if over 18 years old – can give our consent again.



## **Right of withdrawal**

## Our consent is voluntary!

We can withdraw our consent at any time without giving reasons and without any disadvantages arising for us or our child. The legality of the processing based on our consent until the withdrawal is not affected by this. In the case of a withdrawal, the biosamples provided by our child for research will be destroyed and the patient data of our child stored according to this consent will be deleted. If deletion is not possible or not possible with acceptable technical effort, the patient data of our child will be anonymised by deleting the assigned identification code.

We have been informed about the utilisation of our child's patient data and biosamples as well as the associated risks and give our consent within the abovementioned context. We have had sufficient time to reflect, and all our questions have been answered satisfactorily.

We received a copy of the study information for parents and the signed consent form after the informed consent consultation.

city, date		
first name and surname mother (block letters)	signature	mother
city, date		
first name and surname father (block letters)	signature	father
I performed the informed consent consultation.		
city, date		
first name and surname physician (block letters)	signature	physician