

## **Education Sheet for Parents**

### **Dear parents,**

your child was born prematurely, and small for date- with a birth weight less than 1,500 g. We know that many babies can be discharged from hospital, even if they have been born small for date, albeit after an amount of time which appears excessive to the parents. Unfortunately, there is very little valid data, available in Germany, regarding the development of these small-for-date and premature babies in the long-term. The effect of prematurity and low birth weight on the long-term physical and mental development of these babies is particularly unclear. Apart from the low birth weight and prematurity itself, the influence of other factors; such as currently available therapeutic treatments, the genetic constitution and environmental factors on the development of these children is also not known.

### **What is the purpose of the survey?**

The main objective of our survey is to determine the factors, which influence positively the long term progress and development of these babies. This is possible only if we are aware of the exact nature of the treatment, environmental factors and genetic imprinting, which affect the long term growth and development of premature babies. If these are known, it is possible to implement these treatment methods and environmental factors systematically and specifically. This may lead to the future creation of drugs, which simulate particularly favourable genetic characteristics as well as make it possible to eliminate the factors which have an adverse effect. Finally, our survey aims to discover improved treatment modalities, in order to improve the outcome of underweight and premature babies. In order to maintain confidentiality, the data is collected and used exclusively for this survey.

### **How is the survey carried out?**

The data will be collected at three key stages:

1. During the baby's stay in hospital immediately following birth

During the stay at hospital all the essential clinical data of your child (e. g. birth weight and weight at discharge from hospital) will be recorded by the physicians. In order to also examine and analyse the possible genetic influence on the development of the baby, we request your permission to collect two smears of the oral mucosa (the inside of the mouth) of both mother and child, as well as a short piece of the umbilical cord. The smears are taken with a sterile cotton pad and the procedure doesn't cause pain or distress, even to the small baby. The piece of the umbilical cord is obtained while cutting it during the initial medical care of the premature baby. The cord would otherwise be discarded. The human material will not be used for any additional tests and all data protection requirements will be adhered to strictly. We will not ask for blood collection at any point during the survey.

2. At the age of two years

At the age of two years, the motor and neuro development of your child is tested. This examination is recommended anyway for all babies weighing less than 1.500 g at birth; i.e. this is not an examination specially carried out for the purpose of this survey.

3. At six years of age

At six years of age, we plan to examine the mental, intellectual and physical developmental progress (including visual tests).

The follow-up examinations at the age of two and six years will take place in the hospitals where your child has been medically supervised from birth; meaning that you do not have to travel long distances in order to participate in the survey. The results of the follow-up examinations will be discussed immediately afterwards.

Furthermore we will forward to you a questionnaire for parents at all three stages of the survey (during the child's initial hospital stay and at the age of two and six years). These parents' questionnaires have already been answered by more than 17,000 parents, whose children were not born prematurely. As a result, this survey will enable us to find out if the prematurely born infants differ from those born at term; regarding their nutrition, the frequency of consultations etc. We will forward the pseudonymised (i. e. only identified by a number) sheets directly to your private address so that you may complete the questionnaire at your own convenience.

### **Who takes part in the survey? Data storage**

Currently, our survey is the largest one on the long-term development of premature babies that has been conducted in Germany. 50 neonatal departments throughout the country are involved in our survey; and we intend to include about 20.000 neonates over a period of 10 years. We plan on storing the anonymised data over a period of at least 18 years, until the data from the follow-up examinations of the last child enrolled in the survey are completed.

### **Data protection**

It is particularly important for us to protect the personal data of the children participating in the survey. All data will therefore be stored in a pseudonymised format (i. e. all personal data, such as the name and address of participating children are substituted for by a number). We will thus not be in a position to communicate individual results of the genetic examinations to you.

In order to invite you to the follow-up examinations in good time, we request permission to store your address. This address will be verified only with your respective mentoring paediatric clinic and with the registration office; without it being passed to a third party. Both the address data file and the data file including clinical data are protected by extra passwords and encryption, in order to ensure that there is no unauthorised access. It is very important to us to keep you informed about the progress of our survey, and we would therefore ask for your approval to send you a brief report, informing you of the study's progress once a year (on your child's birthday).

All data are completely anonymised immediately after the examination at 6 years of age, i. e. any personal data are completely deleted.

It must be clarified, that participation in this survey is entirely voluntary: no disadvantage, neither to you nor to your child will result from not taking part in it. It will also be possible to withdraw your participation at any point prior to the examination at six years of age, resulting in the destruction of all data (personal and clinical), and all samples. After the final examination, all personal data will anyway be erased.

In the case that you wish to withdraw your participation in this survey, please write to:

The „German Neonatal Network, GNN (Deutsches Frühgeborenen Netzwerk), Klinik für Kinder- und Jugendmedizin der Universität Lübeck, 23538 Lübeck“.

### **Publication of the results of the survey**

By principle, no data about clinics or individual infants will be published, or passed on to a third party. All clinics participating in the survey will receive regular reports on the development and progress of the premature infants that they are caring for. In order to inform as many medical scientists and professionals in the field, as well as others with interest in the results of our assignment, overall conclusions and results will be published in scientific journals, or on the internet.

### **Financing of the survey**

This study is funded exclusively by public subsidies from the Bundesministerium für Bildung und Forschung (German Federal Ministry for Education and Research). It may be the case, that in the future, the results of the survey will have a commercial use; wherein any profits are reserved for the use of the researchers/scientists and university participating in the survey. Your written consent agrees that any financial demands/claims, resulting from the potential commercialisation of the research will be refrained from.

### **Who is responsible for the content and carrying out of the survey?**

Many medical professionals have taken an active role in this survey. The topic has been discussed with representatives from the professional associations for Neonatology, Perinatology and Social Paediatrics respectively; as well as numerous experts for statistical data evaluation. Prior to commencing with the survey, many parents with premature children had been interviewed; and the survey itself has been cleared by „Das frühgeborene Kind e. V.“ (German Federal Association), the largest association for parents with premature infants. Prof. Dr. Wolfgang Göpel (Klinik für Kinder- und Jugendmedizin, Universität Lübeck, 23538 Lübeck), the executive of the survey, is responsible for its implementation and realisation. Should the case be that any damages are inflicted upon a participant of the survey- during its progress, and on account of the behaviour of an employee of the Universitätsklinikums Schleswig-Holstein (UK S-H), the UK S-H will be held liable for any such issues. By carrying out this survey, we hope to better support small-for-date and premature infants in the future. In the case that there remain any questions regarding this survey, please do not hesitate to contact the physician treating your child, or one of the physicians responsible for the survey.

Prof. Dr. med. W. Göpel  
(Studienzentrale Universitäts-  
Kinderklinik Lübeck)

## Declaration of Consent

Herewith I/we give my/our agreement to the participation of my/our child/children

\_\_\_\_\_ born on \_\_\_\_\_

at the survey „Deutsches Frühgeborenen-Netzwerk (German Neonatal Network)“

I have received, read and understood the written information for patients about the survey mentioned above. Purpose and issue of the survey were explained to me in detail – orally and written.

It was pointed out to me that the participation of my child is voluntarily. I have the right to stop/cease the participation at any time and without giving reasons devoid of disadvantages for me or my child.

I was explained and I agree that the clinical progression data of my child and my address are transferred to the survey centre (Paediatric Clinic of the University, Kinderklinik der Universität) and that my address (f. e. in case of a change of residence) will be adjusted at the clinic/hospital treating my child or at the registration office.

I was informed that the taken samples are exclusively used in a pseudonymised or anonymised form in order to research the influencing factors on diseases of neonatal infants and preterm birth. The information about the results of the genetic data cannot be forwarded neither to me nor to the doctor in attendance of my child.

I/we had the opportunity to asking all my/our questions which have been answered satisfactorily and completely.

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Place, Date

Signature of the parent(s)

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Place, Date

Informing doctor (name)

Informing doctor (signature)