



Mother

Surname: _____

First name: _____

Date of Birth: ____ . ____ . _____

Child

Surname: _____

First name: _____

Date of Birth: ____ . ____ . _____

(bleibt bei Einverständnis vor der Geburt frei)

Declaration of consent to participate in the Newborn Screening in order to prevent congenital diseases (remains in the patient chart for disposal of the sender)

The attending physician:

Name	
Address (stamp)	

informed me about the newborn screening to detect congenital hormone, metabolic and hearing disorders (inclusive screening for mucoviscidosis). I have received and read the information flyer for parents. I was informed about the possibilities and limits of this examination - in particular that a suspicious result of the newborn screening is no final diagnosis, but that in this case examinations for clarification are necessary. I was offered the chance to ask questions about all described and recommended screening tests as well as about the procedures. I had enough time to think about questions and concerns. We discussed the following individual issue in regard to my concerns about the newborn screening:

.....

- I declare my agreement** to the participation of my child in the screening for hormone, metabolic and hearing disorders as recommended early detection **newborn screening**.
- I declare my agreement** to the participation of my child in the **screening for mucoviscidosis**.

(In case of denial please mark the corresponding box with a cross at the back of the screening card. I was informed about possible consequences and dangers for my child in case of denial of the newborn screening.)

I ask for further advisement and diagnostics in case of a suspicious result by specialised centres / physicians. Furthermore, I agree that I am contacted directly in case of an emergency situation.

- I avail the right not to know. (includes the hole examination results)
- I want to ignore/ partly ignore the examination result and ask the results to be deleted. (cross out lines that do not apply or add something)

Agreement to store remaining blood samples:

Remaining blood samples are destroyed normally according to the gene diagnostics act after all analyses for the newborn screening have been finished.

- I agree that the disguised blood samples can be used anonymously (no merge with personal data) for research purposes (e.g. further development of screening methods).



Dear parents,

This picture of the data part of a screening card shows which medical and personal data (basically according to specifications of the Children’s Directives) are collected and stored within the newborn / hearing screening (inclusive screening ID). A clear allocation of results and children is possible only by use of the screening ID. A label sheet with the screening ID for your child was therefore pasted into the yellow examination book that is given to every newborn and in this way every child is connected with its corresponding screening ID. In case of questions about the meaning of single fields, please contact your attending paediatrician or obstetrician.

Agreement for data procession

- I was informed that data of me and my child that was collected in connection with the hormone, metabolic and hearing screening (for details see screening card). This is done for purpose of a fast processing and information in case of a suspicious result as the data is send to the screening laboratory resp. tracing centre for hearing screening and can be stored and processed there electronically. A part of the personal data is needed for the billing of laboratory services.
 - In principle, the sender of the blood sample receives the results of the hormone, metabolic and hearing screening (maternity clinic where a physician informed parents and asked for the declaration of consent or respectively the attending physician = responsible physician).§ 8 Gene diagnostics act.
 - The transmission of result photocopies is only possible by the responsible physician and only against signature of the parents or by indication of the corresponding screening ID. The screening ID is inserted into the yellow examination book of every newborn and can therefore only be transmitted by the parents to the attending physician.
 - Results of all analyses are stored acc. to § 12(1) of the above mentioned act for 10 years and are then deleted, as long as the option for the right not to know on page 1 was not chosen.
 - Acc. to § 7 (2) Gene diagnostics act a midwife has the right to take a blood sample on behalf of a physician. The laboratory is only allowed to send the result to the responsible physician acc. to § 11. The physician is only allowed to transmit the result further on only with explicit and written declaration of agreement of the parents.
 - My midwife in charge is allowed to receive a copy of the screening result, in case she took the blood sample for the newborn screening.
- Name of midwife, location:

Declaration of consent of the parents/custodial persons for participation into the hormone, metabolic and hearing screening:

I agree the data of my child and my data can be stored for the indicated purpose, as far as not otherwise mentioned/noted. This declaration of consent can be revoked at any time and with effect on the future. I was informed about the early detection examinations of the hormone, metabolic and hearing screening.

....., Date.....

..... /

Signature of custodial person (mother, father or other custodial person)

¹ Screening ID = distinct identification number composed of 12 figures. Due to mathematical relationship of the single figures the screening ID is protected against misuse and fraudulent use of the stored data.

* The parent who signs the present paper declares that he or she informed the other parent/custodial person about the newborn screening and about the data to indicate. The parent declares further on that he or she is entitled to indicate all requested data. In case that a signature of one parent is missing, please shortly indicate the reason (e.g. sole charge of child).