COPENHAGEN
BABY HEART

INFORMATION FOR PARENTS

ROUTINE HEART EXAM AND BIOBANK IN ALL NEWBORNS

In the Copenhagen area 2016-2018

REMEMBER to schedule an appointment for the echocardiogram after birth: www.baby-heart.dk

You have the option to let your child join a research study conducted by doctors with expertise in heart diseases (cardiologists), child health care (pediatricians) and pregnancy and child birth (obstetricians) at Herlev Hospital, Hvidovre Hospital and Rigshospitalet.

Before you decide if you will let your child take part in the research study it is important that you understand why we conduct the research study and what will happen if you decide to join the study. We will thus ask you to read this information carefully and take as much time as you need. In addition, we will provide oral information and make sure that you have the opportunity to ask any questions you may have. You are welcome to bring a friend or family member along for the oral information.

If you do decide to let your child participate we will ask you to sign a parental permission form. Remember that you do not have to sign the form immediately but have the right to think things through and get back to us with your decision. It is entirely voluntarily to join the research study. If you decide to join the study now you can always change your mind later and retract your consent. It will not affect your child’s future health care if you decide not to take part in the study or to quit the study at a later stage.

Introduction and goal of the study

The term congenital heart defect indicates some kind of abnormal structure af the heart at birth. Congenital heart defects are the most common type of birth defect. In Denmark 450 children are born each year with a congenital heart defect. The defects arise during the development of the heart and we often do not know why. The defects can involve the walls of the heart, the valves of the heart, or the arteries and veins near the heart.

Approximately 70% of children with congenital heart defects will need treatment at some point during their life, while others do not. Most will need regular control with a pediatrician or heart specialist. Today 22.000 people in Denmark have a congenital heart defect.

Severe congenital heart defects are often recognized on routine ultrasounds during pregnancy. Less severe heart defects, and on rare occasions severe heart defects, are not always recognized during pregnancy.

Ultrasound of the heart (echocardiogram) is a safe and efficient way of examining the structure of the heart and is well suited for the diagnosis of heart defects in newborns. If we do find a heart defect, we will make sure that your child gets the proper follow-up and/or treatment at an early stage. We believe that recognition of a heart defect will reduce the complications of a heart defect and give your child the best possible terms. Findings that are not normal will be noted in your child's patient chart.

The goal of Copenhagen Baby Heart is to learn more about how many children are born with heart defects and to investigate whether newborns profit from a thorough, routine examination of the heart shortly after birth. With long-term follow-up of the children, the research study will be able to provide important knowledge about the development of heart disease during life. The goal is to benefit children that are born with heart defects in the future. Analyses of the blood that is collected from the umbilical cord as part of the research study will help us answer questions within a broad spectrum of diseases.

What will happen if you decide to join the study?

All parents of babies born at Herlev Hospital, Hvidovre Hospital or Rigshospitalet from April 2016 to April 2018 will have the option to let their child join the research study. We expect 30.000 newborns to be part of the study. If you do decide to join the study, we may contact you in the future to ask if you would like to participate in further follow-up.

We will ask you if we may draw a small amount of blood (approx. 9 ml) from the umbilical cord after birth. The purpose is to analyze cholesterols, electrolytes and various markers of organ function. However, the blood sample is for research purposes only and these analyses will be performed later on. As this blood sample is for research purposes only, you will not be informed about the results. We will also ask you if we may store a small sample of blood (approx. 3 ml) in a freezer (known as a biobank) for future research. If we do future research involving the blood in the biobank, we will ask for permission from the Regional Ethics Committee at that point. The blood in the biobank will be stored permanently, but you or your child may request the destruction of blood taken from your umbilical cord at any time.

We will ask you to schedule an appointment for an echocardiogram (ultrasound of the heart) within the first 14 days after birth. A sonographer or a doctor at the hospital or at the maternity hotel will do the echocardiogram to take pictures of your child's heart. During the test, your child will lie down on a table or in your lap. We will attach small sensors to the skin with a sticky tape. A recorder (called a probe) will be moved across your child's chest. The recorder makes a video of the heart. The video shows the size of the heart, how it beats and if there are any structural defects. The test takes about 10-15 minutes. It is important that you are present during the exam.

If the echocardiogram is normal you will be told so immediately.
If we see something that is possibly not normal on the echocardiogram, a heart specialist will review the scan and contact you within a few days to let you know the result and if there is any need for further follow-up. You may be asked to attend a supplemental exam. If a heart defects is indeed present, you will be offered the appropriate follow-up with an expert in children's heart diseases (pediatric cardiologist). Information on any needed follow-up or treatment will also be registered in the research project. Furthermore, we may offer you one or more control scan as part of the research project. When clinical follow-up with an expert in children's heart diseases is needed, these control scans will be offered as a supplement.

Scheduling and locations for the echocardiogram

You can choose whether you want the echocardiogram to take place at Herlev Hospital, Hvidovre Hospital or at Rigshospitalet.

	Herlev Hospital	Rigshospitalet **NB! Different locations in daytime and evening.**	Hvidovre Hospital
Time	8-20	8-20	8-20
Location	The maternity hotel, 1st floor by the main entrance.	8-16: The maternity hotel, Aldersrogade 6C, 3rd floor 16-20: Department of fetal medicine, Entrance 4, 1st floor (section 4001), Rigshospitalet.	The maternity outpatient clinic, Building 4, section 433 (next to section 537).

Enrollment and scheduling of an appointment

You may join the study in one of the following manners:

1. By signing the parent permission form when attending the routine ultrasound at weeks 18-20 of pregnancy.
2. By signing the parent permission form before your child is born and e-mail to: hgh-babyheart@regionh.dk
3. By signing the parent permission form before your child is born and mail to: Copenhagen Baby Heart, Hjertemedicinsk afsnit S103, Herlev Hospital, Herlev Ringvej 75, 2730 Herlev.
4. If we have not registered your response to enrollment prior to birth, we may ask you if you would like to join the study during your stay at the maternity ward or maternity hotel.

We encourage you to schedule an appointment for the echocardiogram that suits you and your family. Also, please feel free to contact us for further information on the research study.

- **Phone: 3868 6405**
- **E-mail: hgh-babyheart@regionh.dk**
- **Online scheduling of echocardiogram: www.baby-heart.dk**

Potential benefits, harms and discomforts from joining the study

The overall benefit of the research study is that it will generate important data on the prevalence and importance of heart defects in newborns. In addition, we believe that earlier recognition and appropriate treatment or follow-up of heart defects will be of benefit to the individual child. There are no potential harms from joining the research study. The extra time spent on the echocardiogram may be of nuisance to some. In addition, it is important to recognize that some of the heart defects that potentially will be diagnosed in the research study will not require intervention until later in life and an early diagnosis may cause unnecessary concern.

Preterm termination of the project and exclusion from the project

We do not anticipate any situations resulting in termination of the project before the planned date (April 2018) or situations were individuals will be excluded from the study.

Protection of confidential data

If you join this study, we would put information from the mother's patient chart and from the child's patient chart in our research record. The data we collect include pregnancy and birth complications, inherited diseases in the family and previous medical history. If a child is diagnosed with a heart disease, we will also include information on treatment and follow-up in the research records.

The purpose of collecting these data is to generate information on the natural history and prognosis of congenital heart defects.

Data from medical records will be handled confidentially and in agreement with current Danish laws on data protection. By signing the parental permission form and joining the study, you also give consent to the collection of data from the mother's patient chart and from the child's patient chart.

Budget and funding

The overall budget is 17.741.185 kr. which includes salary to research personnel, equipment, biochemical and genetic analyses etc. The expenses are partly funded by a private foundation and The Danish Heart Association. We will apply for funding for the remaining expenses from both governmental and private funds. Additional funding will be reported to the Ethics Committee and updated in this information. The doctors involved in the research study do not have any competing financial interests.

Payment and reimbursements

You will not be paid to take part in this study.

Primary investigators and initiators of the research study

The research study was initiated by professor Henning Bundgaard, Rigshospitalet and associate professor, Kasper Iversen, Herlev-Gentofte Hospital.

Access to results from the study

The results from the research study will be submitted for publication in international journals of medicine. We expect that the data generated in the research study will be used for research for several years to come.

Contact information

We hope that, after reading this information, you understand why we conduct this research study and what will happen if you decide to join the study. We hope that you feel that you have received enough information to take this decision on behalf of your child.

If you have questions or want to know more about the research study, please feel free to contact Anne-Sophie Sillesen, Department of Cardiology, Herlev-Gentofte Hospital, Herlev Ringvej 75, 2730 Herlev

- **Phone: 3868 6405**
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