



**COPENHAGEN  
BABY HEART**

## **Participant Information**

# **Blood sample analyses and biobank of new-borns' umbilical cord blood**

*Option available to anyone born at  
Rigshospitalet, Hvidovre hospital and Herlev Hospital*

If you want to participate in the project, you can find the consent sheet at [www.baby-heart.dk](http://www.baby-heart.dk) When the consent sheet is filled in, this can either be sent to [hgh-babyheart@regionh.dk](mailto:hgh-babyheart@regionh.dk) or delivered on arrival at the maternity ward

**Please inform the labour and delivery room staff  
that you participate in the study**



We want to ask you whether you are willing to consent to your child's participation in a scientific research study undertaken by cardiologists and obstetricians at Herlev Hospital, Hvidovre Hospital and Rigshospitalet.

Before you give your consent, you must fully understand what the study entails and why it is being conducted. Therefore, we ask that you read this information leaflet carefully.

If you need further clarification, we offer to answer, in person, whatever questions you may have to this leaflet and the study in particular. You are welcome to bring a family member, a friend or acquaintance when you come and see us.

If you decide to give your consent, you will be asked to sign a consent form. Please note that you are entitled to some time to consider whether or not to sign the consent form.

Participation in the study is voluntary. You may at any time and without stating any reason withdraw your consent. This will not affect any treatment you child may be undergoing.

### **Why do we collect umbilical cord blood?**

A large number of diseases may be detected from blood samples. Blood from the umbilical cord is the baby's blood and may therefore possibly be used as early as at the time of birth to detect congenital diseases.

Until now, umbilical cord blood has not been used to screen for congenital diseases, as the reliability of the results of the analyses has been questioned. By – over a number of years – testing blood from approx. 30,000 new-born babies we hope to acquire sufficient knowledge to be able to determine whether in the future umbilical cord blood is suitable for screening for congenital diseases.

## **Taking the blood sample**

All parents giving birth at Rigshospitalet, Hvidovre Hospital or Herlev Hospital may participate. We ask your permission to take a little blood from your baby's umbilical cord (approx. 9 ml) upon birth to test for blood salts, blood lipids and organ function, including liver and renal function. In general, the samples will be analysed at some later date and can therefore not be used to disclose anything about your child's health at the time of birth.

The analyses have only research value, and you will not receive any test results. Surplus blood, if any, will be stored in a biobank for future scientific use.

If future research projects require information regarding your child, permission will have to be obtained from the national committee on health research ethics. We may in the future contact you for additional tests, possibly new samples or examinations. In that case we will have obtained prior permission from the national committee on health research ethics.

The blood samples will be stored permanently but may be destroyed at any time should you or your child request it.

## **Pros and cons**

The argument in favour of this study is that we will obtain knowledge about whether in future umbilical cord blood can be used to screen for congenital deceases.

## **Exclusion from and termination of study**

No circumstances will result in the exclusion of your child from the study.

## **Communication of medical record information**

Relevant information from the mother's and child's medical records will be communicated to the responsible doctors, such as data relating to pregnancy, hereditary diseases and delivery. As regards new-borns with heart disease, information included in the medical records will be communicated on a continuous basis.

Data are collected for scientific medical purposes in order to investigate the natural history and prognoses of congenital diseases. Personal data will be treated as strictly confidential and will always be handled in accordance with relevant confidentiality standards as well as all regulations relating to the processing of personal data and the protection of privacy. Data will be protected in accordance with the Danish act on the processing of personal data and the Danish Health Act. When giving your written consent to your child's participation in the study, you simultaneously consent to data being obtained from the mother's and child's medical records as described above.

## **Financial facts**

The overall study budget is DKK 5,000,000, which covers salaries and blood sample analyses.

## **Research subject compensation**

Research subjects are not compensated.

**Principal investigators**

The principal investigators are Dr. Kasper Iversen, professor, senior consultant and Doctor of Medical Science as well as Dr. Henning Bundgaard, professor, senior consultant and Doctor of Medical Science.

**Access to study results**

The results of the study will be published continuously in international journals. The data collected may be put to scientific use for many years to come, i. e. also after your child has become an adult.

## **Where can I obtain additional information?**

If you want to find out more about the study or have questions, please feel free to contact research secretary Pia Dupont, Department of Cardiology, Herlev Hospital, Borgmester Ib Juuls vej 1, 2730 Herlev.

Contact details:

- **Telephone: 3868 6405**
- **Email: [hgh-babyheart@regionh.dk](mailto:hgh-babyheart@regionh.dk)**

We hope that this information leaflet provides sufficient insight into what it means to participate in the study, and that you will be well prepared to make the decision on whether or not to consent to your child's participation.

Thank you

Henning Bundgaard  
Professor, senior consultant  
Doctor of medical science  
Rigshospitalet-Glostrup Hospital

Kasper Iversen  
Professor, senior consultant  
Doctor of medical science  
Herlev-Gentofte Hospital

Pia Dupont  
Research secretary  
Herlev-Gentofte Hospital



**Name of local contact**

Henning Bundgaard  
Professor, senior consultant  
Doctor of medical science  
Rigshospitalet-Glostrup Hospital  
Tel.: 3545 0512

Kasper Iversen  
Professor, senior consultant  
Doctor of medical science  
Herlev-Gentofte Hospital  
Tel.: 3868 6006