



## Information for parents of infants in neonatal intensive care

**This leaflet tells you about a research study. Before you make a decision please discuss this with your family and friends and do ask any questions you have.**

You, as a parent(s), are being asked for consent for your baby to take part in our Research Tissue Bank, eLIXIR.

## **Why do we need your help with our research?**

The eLIXIR Research Tissue Bank hopes to improve health care for women and their babies. The health of the woman in pregnancy or the child in early life is vitally important for long-term health. To better understand this, we need to look at information from thousands of mothers and babies. As a parent, you may have already been asked for a blood sample for this research, during your pregnancy. As a parent of a baby who has been admitted to the neonatal intensive care unit (NICU), we are asking you to agree to provide blood samples from the baby by letting us use any discarded samples when the tests needed for the clinical care of your baby are complete.

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

eLIXIR will create a sample collection that can be used in studying a range of questions about women and babies' health. We may look at how the mother's health influences the health of her child. For example, if the mother had diabetes in pregnancy, or was taking medicine. We might also want to know how the health of the baby would be affected by being born too early or having difficulties at the time of birth which may affect the health of the child in later life. Mothers' and baby genes might play a role too, and so could environmental pollution. This might influence the baby's health but we don't know exactly how. Sometimes we might want to know about particular genes that were switched on or off when your baby was born.

## **Does my child have to take part?**

No. It is up to you to decide whether or not your child takes part. If you decide your child can

participate, we will ask you to sign a consent form to show you have agreed for your child to take part. You are free to withdraw from the research at any point without giving us a reason.

Your decision about taking part will not affect the treatment you or your child receives.

## **What will happen to your baby if you agree to him/her taking part?**

Your baby needs care in the neonatal intensive care unit and a small blood sample will be needed as part of clinical care. Often, a small amount of blood is left over after the clinical tests are finished. We would like to keep these left-over samples and store them in the eLIXIR Research Tissue Bank. Usually these excess samples are discarded.

All babies have a heel-prick test to check for certain metabolic problems when they are a few days old. The heel prick test involves making a small prick and collecting four spots of blood on a paper card. With your permission, when this test is done we will collect up to 4 extra spots on a separate card to store in the eLIXIR Research Tissue Bank.

All of the samples collected will be anonymised (they will not have your child's name on them) and identified only by a sample number. We will store the sample number in a secure research database. The blood samples will be stored in the eLIXIR Research Tissue Bank licensed under the Human Tissue Act. The eLIXIR Research Tissue Bank will be housed at the National Biosample Centre.

## **Will the samples be tested for genetic disorders?**

As part of future research projects, using biobank samples, including your baby's sample, tests may be undertaken for specific genetic disorders or a range of genetic abnormalities by testing your baby's whole

genetic profile (genome wide sequencing). In the unlikely circumstance that any disorder of clinical significance is found, your GP will be informed.

## **What do I have to do if I take part?**

If you are happy for your baby to take part, and are satisfied with the explanation from the research team, the baby's mother will be asked to sign a consent form, and will be given a copy of this information sheet and the signed consent form to keep.

## **What are the benefits of taking part?**

You and your child may not benefit from taking part, but by joining in you will be helping us understand more about how events in pregnancy, and in infancy can affect health.

## **Are there disadvantages of taking part?**

There is no additional risk to the routine blood spots already being taken.

## **What will happen to the samples my child donated?**

If you decide to donate your child's sample, we will arrange for it to be stored securely in the eLIXIR Research Tissue Bank. Research groups in academic institutions, the NHS and commercial companies in the UK and abroad will be able to apply to use samples stored in the eLIXIR Research Tissue Bank. In all cases, before they are given access to your stored sample and data, the quality of the application will be judged by a group of expert scientists and doctors who work in the same field. Only high-quality applications will be approved.

## **How will your privacy be protected?**

The data collected from your child's electronic patient record (Badgernet) will be link-anonymised which means your baby's sample will be given a

unique code and identifiable data kept separately in a secure electronic system.

Authorised persons (eg representatives from the Sponsors), and regulatory authorities may need to look at information collected about your baby for audit purposes. Confidentiality will be maintained at all times.

## What if there is a problem?

If you have a concern about any aspect of this study, you should speak to the research staff who will do their best to answer your questions.

This study is co-sponsored by King's College London and Guys and St Thomas' NHS Foundation Trust. The sponsors will, at all times, maintain adequate insurance in relation to the study. King's College London through its' own professional indemnity (Clinical Trials) & no fault compensation and the Trust having a duty of care to patients via NHS indemnity cover, in respect of any claims arising as a result of negligence by its employees, brought by or on behalf of a study participant.

## Other information

### Research tissue banks

Many hospitals and universities, including Guys & St Thomas' NHS Trust have created Research Tissue Banks to help with research. Research Tissue Banks can collect and store blood (and other) samples in ways that are suitable for many different types of research. Research Tissue Banks must meet the terms of all current laws and ethical guidelines associated with tissue collection and use for research. This includes having a Human Tissue Authority license and approval from a Research Ethics Committee.

### Will anyone make a profit from my child's stored sample?

Samples will only be used on a non-profit basis. Your sample is a gift and we cannot sell your samples to be used for research. Although we

may charge researchers to cover the time and materials required to process and store the samples.

### **What will happen to the results of the study?**

The results will be published in scientific and medical journals and presented at conferences attended by professionals with an interest in the area. All data will be anonymized before publication.

### **Who is paying for this research?**

The UK Medical Research Council has funded this study.

### **Who has reviewed this research?**

Cambridge East research ethics committee reviewed this study. For more information, see **w:** <https://vimeo.com/257879227> , or to take part, contact, **t:** 020 7188 3641.

## **Contact us**

If you have a complaint, you should talk to your research midwife or doctor who will do their best to answer your questions. If you remain unhappy, you may be able to make a formal complaint through the NHS complaints procedure. Details can be obtained from the Patient Liaison Service (PALS), **t:** 020 7188 8801/3, **e:** [pals@gstt.nhs.uk](mailto:pals@gstt.nhs.uk)

For more leaflets on conditions, treatments and services offered at our hospitals, please visit, **w:** [www.guysandstthomas.nhs.uk/leaflets](http://www.guysandstthomas.nhs.uk/leaflets)