



PARENT/GUARDIAN INFORMATION SHEET

Why have I been asked to read this document?

We are inviting patients at the Royal National Orthopaedic Hospital (RNOH), University College London Hospital (UCLH) NHS Trust and UCL Partner (UCLP) Hospital Trusts to donate tissue and provide access to your clinical notes and imaging to the UCL/UCLH Biobank for Studying Health and Disease.

Please read the following information carefully and discuss it with others if you wish. Please ask us if there is anything that is not clear or if you would like more information.

Why do we want to study your child's notes and imaging (x-rays and scans)?

Research will add to our overall understanding of human disease and the normal functioning of the human body, and may help to design new ways to diagnose and treat disease.

What is the UCL/UCLH Biobank for Studying Health and Disease?

The Biobank is a collection of human material including blood, urine, saliva, sputum, faeces and normal and diseased tissue (e.g. bone, breast, etc) from patients attending various hospitals in the UK and abroad. Samples from the Biobank are used in ethically approved research. Samples donated to the Biobank may be used in research using animal models.

What is the purpose of the UCL/UCLH Biobank for Studying Health and Disease?

The purpose of the Biobank is to have tissue available, now and in the future, for research projects investigating human disease and the normal functioning of the human body.

What will happen to my child's sample?

The Biobank will consider applications from all scientists conducting research in areas covered by the UCL/UCLH Biobank for Studying Health and Disease. Ethical approval is required for any research. Research may be conducted in the UK or overseas and by either public sector or commercial organisations. In order to defray some of the costs of running the Biobank, researchers may be charged for the use of tissue.

Does my child have to take part?

No. Whatever your decision, it will not affect any treatment or care your child receives in this or any other hospital, now or in the future.

What will it involve if I decide to permit my child take part?

On behalf of your child, you will be asked to sign a consent form that allows:

- clinical information to be extracted from your child's notes and imaging (x-rays and scans) from any hospitals they have attended or will attend in the future
- your child's data to be stored on a secure database in a coded/anonymised form
- storing a small amount of tissue, that was taken for diagnostic purposes as part of routine clinical care but which is surplus to diagnostic requirements, for research projects including genetic research. Genetic analysis of your child's tissue and blood often explains why certain diseases develop may help to decide on treatment
- donation of your child's blood, up to 50ml (6-8 teaspoons). Taking a blood sample may result in minor discomfort and slight bruising
- collection of urine, saliva, sputum and/or faecal specimens

All these samples will be collected when your child visits his/her hospital. We will make every effort to take the blood sample whilst your child is under anaesthesia or having a routine blood test. The saliva sample is taken by gently stroking the inside of your child's cheek with a cotton swab or by spitting into a suitable container. We may



ask for any of the above samples on more than one occasion but you can refuse at any time without giving a reason and without your child's medical care being affected.

What are the advantages and disadvantages of my child taking part?

There are potentially no advantages to your child if they participate in research but it may help others in the future. You will not receive a financial reward. Donated tissue is considered to be a 'gift' to the Biobank.

What will happen if new information becomes available?

We do not expect to report the results from the research on your child's samples to you although very exceptionally a finding might be reported to your child's clinical team if it were considered that it may have an impact on your child's clinical treatment, and they would discuss this with you.

Will my child's information be kept confidential?

Yes. All information about your child and their tissue samples will be treated in the strictest confidence. No information about your child can be traced back to them by the researcher.

Results from genetic studies will be placed on a database to which only authorized individuals have access. Before having access to your child's clinical information and/or tissue samples researchers must agree to conditions which safeguard your child's confidentiality. You will not be informed of the results of genetic testing and donating tissue to the Biobank will have no impact on your child's medical insurance.

Family members

It is sometimes useful to have blood samples or other samples from family members as this allows us to study the impact of genetic and environmental factors on the development of a disease. Therefore in some instances we may ask you to consent to allow us to contact your family members (parents/grandparents/ cousins etc) and we would contact you directly to ask you but you can refuse this request without giving an explanation.

What if there is a problem or I require further information?

If you would like further information or you have concerns about this research at any time you can:

- discuss it with your doctor or nurse
- contact the Person Designated on 020 8909 5354, who will try to answer your question or will arrange for you to speak to an appropriate person
- Normal NHS complaints procedures will apply

What will happen if I do not want my child to carry on with the study?

You are free to withdraw your consent at any time. This means that researchers will no longer be able to access your any of your child's notes and images, and your child's tissue samples in the Biobank will be destroyed. You do not have to give a reason for changing your mind. However, if some data have already been used it is not always possible to recall it.

To withdraw your consent, please contact the Person Designated on 020 8909 5354 or write to us at UCL/UCLH Biobank for Studying Health and Disease, Department of Histopathology, Institute of Orthopaedics and Musculoskeletal Science, Royal National Orthopaedic Hospital, Brockley Hill, Stanmore, Middlesex, HA7 4LP.

Who is organizing and funding UCL/UCLH Biobank for Studying Health and Disease?

The Biobank is overseen by the Joint Research Office of UCL/UCLH. The cost of operating the Biobank will be funded by sponsors.

Who has reviewed the project?

The UCL/UCLH Biobank for Studying Health and Disease has been given a favourable ethics opinion from the National Research Ethics Service (NRES) Committee Yorkshire & The Humber – Leeds East. The REC number is 15/YH/0311.

Thank you for taking the time to read this information.