

(To be printed on institutional headed paper)

**Children's Cancer and Leukaemia Group
Tissue Bank (2008 BS 01)
Information sheet on consenting to storage and use of tissue
samples for research**

INFORMATION SHEET FOR PARENTS

(Version 3.0, 6th April 2011)

Why are tissue samples needed for research?

Great progress has been made in the last twenty years in the treatment of childhood cancers, including leukaemias. But we still have a lot to learn to improve diagnosis treatment, and prevention.

Nearly all treatments used today are based on the results of previous research. Most children's cancer research in the UK and Ireland is carried out by members of the Children's Cancer and Leukaemia Group.

The children's cancer service in the UK and Ireland is divided into 21 regional centres including **(local centre name)**. Here in **(local centre name)** we carry out a variety of research projects into various types of tumours and leukaemias in children. We also work with other hospitals in the UK and elsewhere carrying out research into children's cancer and leukaemia.

Many research projects need to use samples of tumours or leukaemia cells and also sometimes samples of normal tissues (usually blood). Scientists use these samples to try to understand what has gone wrong inside the cancer cell. For example, using tissue samples has allowed researchers to discover that cancer cells that look the same down a microscope may in fact behave very differently and require different treatment.

To help with such research, the CCLG runs a national Tissue Bank. This stores samples of tumour, leukaemia cells and normal tissue (such as blood or bone marrow). Samples can be used in approved research projects. Research on tissue samples may not directly benefit your child now, but it may help children with cancer in the future.

What is involved in consenting to tissue banking?

Consent for the CCLG Tissue Bank covers storage and use of tissue samples for research. ***It does not mean that anything extra to normal treatment will be done to your child.***

Tissue samples stored in the Bank are those "left over" after operations, biopsies or other procedures, when doctors treating children have finished with the samples and have no further need for them for clinical purposes.

Doctors are not asked to obtain extra samples of tissue for research while they are treating your child.

The samples stored in the Bank are small – perhaps the size of a sugar lump, or a teaspoon or two of blood or bone marrow. The samples are usually frozen or are stored on specially prepared slides.

Information about the diagnosis and treatment of the child from whom the sample came is kept alongside the sample, but is completely anonymised. Samples in the Bank are labelled only with a special code, not with your child's name. Researchers are not given any personal information that could identify your child.

What if extra samples of “normal” tissue are wanted?

Families are usually asked if they would consent to an extra blood sample or sample of bone marrow being taken so that researchers have a sample of “normal” tissue as well. These samples can usually be taken during the same procedure when samples are being taken as part of treatment so should not involve any extra pain, discomfort or inconvenience.

You can decide whether you are happy to consent to the extra sample of “normal” tissue being taken – this is separate to consenting to tissue banking.

Tissue will not be taken or stored for research without consent.

Who gives consent?

Under the Human Tissue Act 2004, anybody under the age of 18 may give consent to storage and use of his or her tissue for research if s/he is “competent”, regardless of age. If your child is willing and able to consent, we will usually ask the parent(s) to consent as well.

Some young people might prefer their parent(s) to give consent, even if they are “competent”. Or there might be some doubt over whether they understand what's involved, perhaps if they are too young or if there is a lot going on at the time. If the child prefers not to give consent or is not “competent” to give consent, the parent(s) can give consent.

What will happen to my child's tissue samples if consent is given for storage and use for research?

Tissue samples will be initially stored here at **(local centre name)** and then transferred to the CCLG Central Tissue Bank in the Newcastle Biomedicine Biobank where they will be stored on behalf of CCLG and issued to approved researchers. Tissue samples may sometimes also be sent abroad for approved research projects.

Tissue samples may be used in different research projects to help improve our understanding of children's cancers and leukaemias. Samples could be stored for many years, as they may be used for research a long time in the future. The samples could be used in more than one research project which may include genetic research but you will be asked to consent once only for storage and use of the samples for research.

All research studies using the samples must be scientifically and ethically approved. The CCLG has a special committee of scientists to make sure that any researchers requesting samples are proposing a suitable project.

The samples are mostly used by university-based researchers. However, if there are good reasons for allowing the samples to be used in research by commercial organisations or in commercially-sponsored research, approval for this may be given after scientific and ethical review. It is also possible that patents could be taken out on scientific discoveries based on the research.

Will research on tissue samples be confidential?

Tumour and blood samples are stored under strict anonymity. In order to make best use of the samples, researchers usually need to know the diagnosis, treatment, and progress of the children who give the samples. However, they do not need to know children's names or any personal details. To maintain anonymity, the samples are given a code.

The link between the code and your child's tissue samples would be kept at **(local centre)** and also either the CCLG Co-ordinating Centre in Leicester or the National Childhood Leukaemia Cell Bank Database in York. This means there is a link between the samples and up-to-date clinical information kept by the CCLG about children being treated for cancer and leukaemia. In accordance with the Data Protection Act, strict confidentiality is maintained.

Sometimes samples may be sent overseas to researchers in countries that have different data protection laws to those in the UK. However, they would never be sent any information that could identify your child, only an anonymous code.

How do I know that my child's samples will only be used for ethically approved medical research?

Samples can only be used by researchers whose projects have gone through a strict approval process. For projects using samples from the CCLG Tissue Bank, this includes scientific review by experts appointed by the CCLG.

Samples may also be used in local projects based in your own hospital. Such projects will also need to be independently reviewed to ensure their scientific quality and must also have approval from a Research Ethics Committee.

Will I be told the results of individual research tests on my child's samples?

In line with normal practice, individual results of research on your child's samples will not be given to you or your doctors. Research tests do not form part of your child's medical treatment or records and so individual feedback is not given. However, if in the future the research shows that there is a test or treatment that might be useful to your child or family, then your child's doctors will discuss this with you.

The overall results of the research projects may be published as research papers in scientific and medical journals, and general results of research on tissue samples will be published regularly in CCLG newsletters and/or elsewhere.

What are the possible risks of consenting to storage and use of tissue samples for research?

Consenting to tissue banking means that you are consenting to storage and use of tissues for research. As far as we know, there are no risks associated with this.

Are there any possible benefits?

Consenting to the storage and use of tissue samples for research is unlikely to have direct benefits for your child. But researchers can learn from the tissues and may be able to help improve diagnosis, treatment, and maybe even prevention of cancer in children in the future.

Your child's samples could be used in research that might lead to researchers or drug companies inventing new treatments or tests for cancer, which could be covered by a patent. You and your child would not receive money from any discoveries made from research on tissue samples.

Do I have to consent to use of tissue samples?

No. You are under no obligation to consent for storage and use of tissue samples in the CCLG Tissue and Leukaemia Banks. It is entirely voluntary. If you prefer not to consent, this will not affect the care given to your child in any way. Whether or not you decide to give consent, your child will still receive the best available treatment.

If at any time in the future you change your mind and do not wish the tissue to be used for research please let your doctor know. Any tissue samples that remain will be disposed of, usually by burning them (incineration).

What should I do if I have any concerns about consenting to storage and use of tissue samples for research?

If you have any problems, concerns or other questions, please speak to the medical or nursing staff who are involved in your child's care, or you can contact one of the following persons managing the CCLG Tissue and Leukaemia Banks:

Chief Investigator: Dr Keith Brown, Reader in Molecular Pathology, University of Bristol,, School of Cellular and Molecular Medicine, Medical Sciences Building, University Walk, Bristol. BS8 1TD.

Tel: 0117 3312071

Email: keith.brown@bristol.ac.uk

Co-Investigator: Dr Brenda Gibson, Consultant Paediatric Haematologist, Royal Hospital for Sick Children, Yorkhill, Glasgow. G3 8SJ

Tel: 0141 201 9307

Or, Dr (Local consultant in charge)

Nurse contact (local)

NO TISSUE WILL BE STORED SPECIFICALLY FOR, OR BE USED IN RESEARCH WITHOUT YOUR AGREEMENT.

WEBSITE COPY FOR REFERENCE ONLY