



The Children's Cancer and Leukaemia Group

Tissue Bank (2008 BS 01)

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Confidentiality statement: This protocol is for research purposes only, and should not be copied, redistributed or used for any other purpose. All CCLG employees and members involved with this study shall not disclose or use data, records or other information for any purpose other than assessing the performance of the bank, without the prior approval of the CCLG Biological Studies Steering Group.

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Change Log

Amendment 3: Approved 5th May 2011

Front cover	The word 'Childhood' in the title 'Childhood Cancer and Leukaemia Group' has been changed to 'Children's'. This change is reflected throughout the protocol
Entire Protocol	<p>Following names of organisations and supporting bodies have been changed throughout the protocol:</p> <ul style="list-style-type: none"> • CCLG Data Centre has been changed to CCLG Coordinating Centre. • CCLG Division of Leukaemia and Lymphoma has been changed to NCRI CCL Clinical Study Group Leukaemia Subgroup. <p>Centralisation of the CCLG Tissue Bank will be at the Newcastle Biomedicine Biobank at Newcastle University. This is referred to as the CCLG Central Tissue Bank throughout the protocol.</p> <p>Reference to 'Appendices I, III and IV' have been removed throughout the protocol (Amendment 2 (non-substantial): 21st December 2010).</p>
Contact Details	<p>Change of Chief Investigator.</p> <p>Change of Chair of Biological Studies Steering Group.</p> <p>Change of Tissue Bank Manager/ Biological Studies Coordinator.</p> <p>Added members' details of the Newcastle Biomedicine Biobank.</p>
Section 1.0	Reference to CCLG Central Tissue Bank.
Section 2.1	Reference to CCLG Central Tissue Bank.
Section 3.0	CCLG Centres has been changed to 'centres affiliated with CCLG'.
Section 4.0	Reference to MRE02/10/52 has been deleted.
Section 4.1	Banking of existing holdings has now been implemented.
Section 5.1	<p>Reference to CCLG Central Tissue Bank.</p> <p>Added more detail on banking paraffin wax-embedded tissue.</p>
Section 6.1	<p>Deletion of Barts/The London (closed paediatric oncology centre) and Leicester (no longer register samples as do not undertake surgery at this site) banking centres.</p> <p>Change in follow up data collection, at 6 months from diagnosis.</p>
Section 7.0	<p>Removed details on direct links to trial data as the CCLG Coordinating Centre no longer coordinate clinical trials.</p> <p>Removed details on Biomedical scientists having access to data as no longer supported by the CCLG Tissue Bank.</p>

Section 8.0	Amended details of the patient tissue and data storage locations.
Section 8.1	Deleted reference to congenital anomalies.
Section 9.0	More details added about the approval of biological studies.
Section 10.1	Amended details on access to samples for research from the CCLG Central Tissue Bank.
Section 11.1	Amended details on returning samples to the CCLG Central Tissue Bank.
Section 12.0	More details added about publications that arise from research undertaken on tissue used from the Tissue Banks.
APPENDIX I (Parent/Patient Information Sheets)	<p>Previously listed as APPENDIX II.</p> <p>All information sheets amended to reflect changes in names of organisations, location for the storage of tissue and details of the Chief Investigator of the CCLG Tissue Bank.</p> <p>Added a 'Patient/Young Adults Information sheet' and 'Summary information sheet on consenting to tissue for research'.</p>

Amendment 2 (non-substantial): 21st December 2010

APPENDICES	The following appendices have been entirely removed and separately amended and issued:
APPENDIX I	Sample Registration Forms
APPENDIX III	Application for a CCLG Biological Study
APPENDIX IV	Procedure for approval of a CCLG Biological Study

Amendment 1: 9th June 2009

Section 5.1	More detail added to pathology guidelines
Section 6.1	Reference to Follow up form (Form D)
Section 9.0	<p>The following bullet points have been deleted</p> <ul style="list-style-type: none"> • The chief investigator for the research proposal is based in the UK • There is no transfer of tissue outside the UK
Section 9.1	New subsection giving further details on 'local research'
APPENDIX I, Form B	The words 'peripheral blood' have been removed to clarify that samples can also be taken from patients central venous line if they have one <i>in situ</i> .
APPENDIX I, Form D	New form requesting basic patient information on registered samples, i.e. whether patient is also on a clinical trial and status of patient (alive or dead).

APPENDIX II, Patient/Parent Information sheets (Page 3)	Insertion of “(which may include genetic research)”.
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APPENDICES:

APPENDIX I	Parent/Patient Information Sheets and Consent Forms
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CCLG Tissue Bank

1.0 Aims

- To create, with appropriate consent, a national network of stored tissue samples from children with cancer, leukaemia and some benign tumours suitable for use in biological research projects that aim to improve understanding and treatment of childhood cancer and related conditions.
- To enable all centres treating children with malignancy to routinely take, store, and despatch to a central bank, with appropriate consent, tissue samples surplus to diagnostic requirements for use in present and/or future research.
- To make available to researchers, through a centralised scientific and ethical review process, suitable biological tissues from the Children's Tissue and Leukaemia Banks for projects approved by the Children's Cancer and Leukaemia Group (CCLG) Biological Studies Steering Group.
- To allow the storage of tissue samples for local research studies that have local scientific and ethical approval. The consent to store and use this material will be obtained through the generic CCLG consent procedure.
- To transfer registered samples to the CCLG Central Tissue Bank in the Newcastle Biomedicine Biobank for storage, quality assurance and prompt release to researchers.

2.0 Background

Although considerable progress has been made in the treatment of childhood cancer, future advances are likely to be made through a greater understanding of the underlying biology.

To undertake studies of the biology of childhood malignancies, it is vital to have access to large series of samples of childhood tumours and leukaemias. These samples need to be of high quality, be pathologically verified, and be linked to relevant clinical data. At present many biological studies, especially of potential molecular prognostic factors, suffer from small sample numbers. The value of tumour or leukaemia samples to research is greater if the children from whom they are obtained are treated on disease-specific protocols and links to clinical characteristics and outcome data are maintained. To fulfil this need the CCLG Tissue Bank was created in 1998.

Representatives of families and particularly the National Alliance of Childhood Cancer Parent Organisations (NACCPO) and the CCLG Patient Advocacy Committee have been closely consulted about all aspects of tissue banking, and particularly the issue of consent. Almost universally, parents wish to see some good come out of the difficult situation they find themselves in. There is widespread support, therefore, from families for consent for the use of their child's samples in research to further understanding of their child's and other children's cancer. Indeed, many expect that such research would be carried out routinely. There is also considerable support for the concept of one single consent, which would allow future use of samples in multiple research projects, being reassured by the knowledge that all such research carried out on human tissues must have appropriate scientific and ethical approval.

2.1 CCLG Tissue Bank

The CCLG Tissue Bank has been in operation since 1998. After discussions with UK paediatric pathologists and neuropathologists, the Bank was established as a 'virtual' network of frozen tumour samples, stored in local pathology departments but registered centrally with the CCLG. Since 2001, the Bank has also registered paraffin embedded blocks. Subsequently a centralised bank of constitutional DNA has been established in the DNA Laboratories in St James' University Hospital, Leeds. Creation of the Bank was facilitated by a pump-prime grant from The Lisa Thaxter Trust with subsequent support by a grant from Cancer Research UK. In November 2010 Cancer Research UK (CRUK) agreed to fund the transfer of stored samples in centres to the CCLG Central Tissue Bank at the Newcastle Biomedicine Biobank, and the continued transfer of prospective registered samples.

Since its inception, over 9,000 tissue samples have been registered with the Bank. These have been used to support research projects approved by the CCLG Biological Studies Steering Group and a Multi-centre Research Ethics Committee (MREC). The consent process also covers use of locally stored samples for in-house research projects, subject to local scientific and ethical approval procedures.

Clinical trial investigators are encouraged to utilise the CCLG Tissue Bank consent process for collection and storage of samples from patients entering a clinical trial. This allows appropriate consent to be obtained so that these valuable specimens, which can be linked to ongoing clinical outcome data, can be used not only for the current biological study assigned in association with the clinical trial, but also for any future studies that may become relevant as new discoveries are made. Release of such samples for any future research projects is dependent on the scientific approval of the project by the CCLG Biological Studies Steering Group and ethical approval by the appropriate ethics committee (where necessary).

2.2 Childhood Leukaemia Cell Bank

In 2003 a new national treatment trial for children with childhood acute lymphoblastic leukaemia (ALL), ALL 2003, opened. This incorporated the measurement of minimal residual disease (MRD) by molecular methods in its risk stratification. With support from the Leukaemia Research Fund, four laboratories working as a virtual laboratory to common protocols were set up. The skills and logistical strengths of the UK MRD network laboratories were ideally suited to establish a quality assured cell bank. Bone marrow samples are sent from all newly diagnosed patients with ALL to these laboratories and surplus cells are banked with consent for future research.

It is planned that the same mechanism will be used for future clinical trials in childhood leukaemia. The samples may be sent to additional laboratories approved by the NCRI CCL Clinical Study Group Leukaemia Subgroup

3.0 Patient Eligibility

Inclusion Criteria

- All patients in the United Kingdom and Ireland, treated in a centre affiliated to the CCLG in whom the diagnosis of cancer or leukaemia is suspected and who are having a diagnostic or therapeutic tissue sampling procedure are eligible to have tissue taken and stored in the Bank.

- There is no strict upper age limit as some samples may come from patients aged > 20 years but with paediatric-type cancers.
- Documented informed consent from parent/guardian and/or patient where appropriate and the patient is competent.

Exclusion Criteria

- Patients known to be infected with HIV, hepatitis B or any other agent posing an infection risk from unfixed material.

Note: Samples from the Tissue Bank will be released on the understanding that they are reasonably believed not to contain a dangerous or infectious substance (although all the usual precautions for handling unscreened human material must be observed).

4.0 Consent

The CCLG Tissue Bank consent forms and patient/parent information sheets were created in consultation with Professor Mary Dixon-Woods (University of Leicester) following her research into the views of patients, parents and professionals on tissue banking for research.

Consent will be requested from parents and/or patients, where appropriate, for the collection, storage and present or future use of tumour or leukaemia samples, surplus to diagnostic/medico-legal needs.

Any future use of tumour or leukaemia samples would not require separate consent but would be dependent on appropriate scientific and ethical approval (See Section 9.0) of the particular research project(s).

The Children's Tissue and Leukaemia Banks consent process includes permission to use the material, for collaborative research with overseas researchers, providing each research project has received appropriate scientific and ethical approval. The consent process also covers use of locally stored samples for in-house research projects, subject to local ethical approval procedures.

All solid tumour and non-trial leukaemia patients will be consented using the information sheets and consent forms within the protocol. Leukaemia patients registered into a clinical trial will be consented using the approved processes embedded within the protocols.

4.1 Existing Holdings

Diagnostic specimens are currently stored in accredited histopathology departments across the United Kingdom as part of the NHS patient record. With the introduction of the Human Tissue Act, 2004, all such material held before the day on which the Act commenced (1st September 2006) for use for a scheduled purpose, are classified as 'existing holdings'. Section 9 of the Human Tissue Act indicates that such existing holdings are exempt from the consent provisions of the Act. Thus existing archival holdings of pathological specimens can be stored and used without the need for specific additional consent under the terms of the Human Tissue Act.

Since such collections of diagnostic biopsies and resections, mostly in the form of archived paraffin wax blocks and slides, represent a considerable resource for the potential investigation of rare childhood tumours, the banking of such existing holdings is now incorporated into the CCLG Tissue Bank. In all such cases, banking of these samples will be

in association with basic outcome data and any data collected as part of a national clinical trial only.

In these cases, best practice will be observed and material will remain in the diagnostic departments in case subsequent diagnostic or other review is required. In order to maximise the usefulness of this resource, the CCLG Biological Studies Steering Group will prioritise the banking of archival specimens, with priority being given to cases included in previous clinical trials and subsequent banking priority will be decided by the CCLG Biological Studies Steering Group.

5.0 Sample Selection and Storage

The type of material to be stored in the Bank includes:

- Tumour tissue
- Uninvolved tissue
- Normal tissue
- Benign tissue
- Bone Marrow
- Leukaemic Cells
- Peripheral Blood
- Cells or tissues on microscope slides
- Urine, CSF, Serum

Once collected this will be stored as:

- Unfixed, frozen
- Unfixed, fresh
- Fixed and embedded blocks and slides
- Extracted derivatives (such as DNA, RNA or protein)
- Extracted tissue/cellular fractions (including cell lysates, nuclear lysates or purified cell populations)

5.1 All Solid Tumours (and non-trial leukaemias)

The local pathologist will primarily work to locally approved Standard Operating Procedures for the sampling and storing of frozen tumour. Supplementary CCLG guidelines are available and pathologists are encouraged to adhere to these providing they comply with local procedures.

Both frozen and paraffin tissue can be banked. To ensure the maximum potential of samples are banked, it is a good method of practice to always freeze at least one aliquot of tissue from all fresh paediatric tumour samples received into the laboratory, if sufficient is available surplus to the diagnostic requirement. Tissue is then subsequently available once consent for banking has been confirmed.

An aliquot of tissue banked should ideally be 0.5-1.0mm³. In some cases the sample size may be smaller, such as with needle core biopsies, but the tissue is still suitable for banking. It is recommended that samples are snap-frozen in liquid nitrogen as soon as possible following receipt, and either stored in cryovials (e.g. 2ml) in liquid nitrogen vapour or -80°C freezers. Methods are dependent on local resources available. Samples will be held locally prior to transferring to the CCLG Central Tissue Bank in the Newcastle Biomedicine Biobank.

Pathologists will also be encouraged to identify and provide a representative sample of formalin fixed, paraffin wax-embedded tumour tissue (as paraffin blocks or slides). Some paraffin blocks will be sent to the CCLG Central Tissue Bank in the Newcastle Biomedicine Biobank, and returned once sections for research have been obtained. This will only be possible where sufficient material remains after satisfying the requirements for local diagnosis, medico-legal purposes and pathology review. When it is not possible to despatch paraffin blocks, sections and/or slides will be sent for staining and storage.

5.2 Leukaemia (clinical trial patients only)

Bone marrow samples taken at diagnosis and during treatment, from which surplus cells and/or DNA will be stored according to Standard Operating Procedures, are sent to one of the four MRD laboratories assigned by geographical region (Barts/The London, Bristol, Glasgow and Sheffield). These reference laboratories have the capacity to store samples of all types of leukaemia. All samples will be 'linked anonymised' and retain links to clinical data. The quality of cells/DNA will be audited. In some cases material may also be stored locally, for local research projects and will not be included in the national database.

6.0 Registration of Samples

6.1 Solid tumours (and leukaemias registered with CCLG)

Each sample will be given a unique identifying number consisting of a centre number prefix followed by the case and then sample number. The centre number prefixes are as follows:

1.	Aberdeen	12.	Leeds
2.	Not allocated	13.	
3.	Belfast	14.	Liverpool
4.	Birmingham	15.	Manchester
5.	Bristol	16.	Newcastle
6.	Cambridge	17.	Not allocated
7.	Cardiff	18.	Nottingham
8.	Dublin	19.	Oxford
9.	Edinburgh	20.	Royal Marsden
10.	Glasgow	21.	Sheffield
11.	G.O.S.	22.	Southampton
23.	UCLH	24.	King's College

The local pathologist, or other delegated person, will complete the registration form (Form A) and send it to the CCLG Coordinating Centre, Leicester, to register the sample. It is the responsibility of the local centre to ensure that appropriate informed consent has been obtained and to confirm this on Form A. A copy of the pathology and/or cytogenetics report will be sent to the CCLG Coordinating Centre to be anonymised and annotated with the tissue bank number. Paraffin blocks will be registered on a separate form from frozen tissue, even if available from the same patient. A follow up form (Form D) will be sent to centres for completion 6 months and 3 years from diagnosis to update on patient status and clinical trial information.

6.2 Leukaemia (clinical trial patients only)

Each sample will be identified by a trial/study number. A banking form, that has previously been ethically approved, will be completed indicating that consent has been obtained. This form is sent to the laboratory dealing with the sample. The laboratory enters the consent details onto the database. The trial number will link the specimen to its clinical and

cytogenetic information. The database allows full tracking of consent, and protocols will be in place to destroy samples without satisfactory consent. This mechanism will be used as a model for future leukaemia studies which may be allocated to different trial laboratories.

6.3 Constitutional DNA and Normal Tissue

If normal tissue, obtained under any of the above circumstances, is available to the pathologist, this can be stored and registered in the same way as the tumour,

Constitutional DNA will be collected by a centralised process for sending, extracting and storing DNA from patient blood samples. A minimum of 5ml of blood will be sent to the DNA Laboratory, Leeds (see Contact details) in a protected EDTA container by first class post. The consent for taking, processing and use of this sample is covered by the CCLG Tissue Bank Consent. Samples being sent to Leeds for DNA extractions should be registered using Form B.

Constitutional DNA stored in Leeds will be coded. Once a month details of stored DNA are provided to CCLG. Coded DNA will be released directly to approved projects, the costs of transport being met by the researcher. Where possible, one aliquot of DNA is released for each project, thus maintaining material for future research.

7.0 Protection of Patient Identification

The specimens held in the CCLG Tissue Bank have much greater scientific value if they are stored as 'linked anonymised' samples rather than fully anonymised. This is because so much of the clinical relevance of potential research projects lies in the ability to link molecular characteristics to clinical parameters, especially outcome

The only sites of linkage between the individual specimen's tumour bank number and patient identifiers are at the CCLG Coordinating Centre, other relevant Clinical Trials Units, Leukaemia Cell Bank databases, the DNA Lab, and at the patient's local hospital. In each location the link is held in secure databases and only accessible to limited numbers of staff, all of whom are required to sign a confidentiality agreement regarding handling of patient information as part of their contract of employment. Researchers have no access to individual patient identifiers.

8.0 Data Management

Patient and tissue data will be recorded and maintained in the following locations:

Solid Tumours

CCLG Co-ordinating Centre, Leicester

DNA Laboratory, St James' University Hospital, Leeds

Newcastle Biomedicine Biobank, Newcastle University, Newcastle Upon Tyne

Leukaemia

National Childhood Leukaemia Cell Bank Database, LRF Epidemiology and Genetics Unit, York; Childhood Cancer Research Group, Oxford

8.1 Data Release

Only the following data will be provided “up front” to researchers:

Solid Tumours (and non-trial leukaemias)

- CCLG tissue banking sample identifier number
- Local pathological diagnosis.
- Whether specimen is from primary tumour or a metastatic site (specified as e.g. involved lymph node or bone marrow) and whether it is at diagnosis, during treatment or at relapse.
- If matching normal tissue is available, the type of tissue will be specified (e.g. blood, lymph node, adjacent normal kidney, etc).
- Where necessary for sample selection for a particular study, patient gender; age at diagnosis; tumour site, stage and histological sub-type may be released.

Leukaemia (trial patients only)

- Samples will be held in the MRD or other laboratories with a trial/study number, which links them to their clinical details.
- On the Leukaemia Cell Bank database website will be published aggregated information about the number of samples available for research by type of leukaemia and immunophenotype.
- Appropriate, anonymised, clinical and other information, stored as part of the centralised data management system, will be released to researchers. The researchers will not contact the other organisations involved.

Studies which require additional clinical information for correlation of molecular genetic findings with clinical parameters will be handled as follows.

All such studies will have been submitted for scientific review by the CCLG members of the Biological Studies Steering Group, independent expert reviewers and the appropriate CCLG Interest Group as part of the procedure for release of biological material. It is expected that the molecular analysis will be carried out 'blind', with the minimum clinical data required for sample selection, available to the researcher.

Once the molecular analysis is completed on the cohort of tumour samples, the principal researcher should contact either the CCLG Tissue Bank Manager/Biological Studies Co-ordinator or Co-ordinator of the Leukaemia Cell Bank Database to arrange for analysis of clinical correlations to be undertaken. This will be carried out in line with the CCLG and Childhood Leukaemia Cell Bank agreed procedures for Access and Release of Data. No personal identifiable information will be released. The database for leukaemia patients is retained at Trials Units under the auspices of the NCRI CCL Clinical Study Group Leukaemia Subgroup.

9.0 Process for Approval of Research Projects

Samples from the Tissue Bank will be made available to researchers if granted scientific approval by the CCLG Biological Studies Steering Group. Research proposals submitted to the CCLG Biological Studies Steering Group will undergo the following approval process:

All proposals will be reviewed for their scientific merit, feasibility and clinical relevance. Proposals will be reviewed by a scientific panel comprising at least 2 members of the CCLG Biological Studies Steering Group, by at least 2 independent expert reviewers, (unless the

application has already been approved for funding by a recognised funding agency) and, where appropriate, the Chair of the relevant NCRI Clinical Study Subgroup or CCLG Interest Group. (If an application already has approval from the relevant NCRI Clinical Study Subgroup or CCLG Interest Group, a letter of approval should accompany the application). Responsibility for final scientific approval rests with the CCLG Biological Studies Steering Group.

Projects approved by the CCLG Biological Studies Steering Group which fulfil all the following criteria, will not require further submission to a research ethics committee.

- The research is restricted to research on the prevention, detection, diagnosis, treatment and patho-physiology of children's cancer
- The proposal has been granted scientific approval by the CCLG Biological Studies Steering Group
- The research will only use samples for which written consent has been obtained from patient, parent or guardian for storage and use of these samples for research purposes or samples stored for research with the previous agreement of Trent REC.
- No patient identifiable information is to be released to researchers
- The research does not have direct impact on individual patient care nor is there feedback of results to individual patients

If any of the above criteria are not met, the project will be submitted to an appropriate REC for approval before samples can be released from the Bank. If a project already has REC approval, this will be confirmed by submission of a copy of the NRES Application and letter of approval to the CCLG Biological Studies Steering Group.

An annual report will be submitted by the CCLG Biological Studies Steering Group to Trent REC summarising all approved research projects for which samples have been released.

Full details of the application and approval process are available to researchers on the CCLG website (www.cclg.org.uk) or via the CCLG Tissue Bank Manager/Biological Studies Co-ordinator (see Contact details) or for Leukaemia samples on the Childhood Leukaemia Cell Bank website (www.cellbank.org.uk).

9.1 Local Research

Sometimes a project arises in a centre which would benefit from local samples which have already been registered in the Bank. The centre can either

- Apply through the above process for these samples to be released from the CCLG Tissue Bank. The advantage of this is that if approved the project comes under the Ethics Approval for the CCLG Tissue Bank and the centre could access further samples from CCLG Central Tissue Bank if needed in the future.
- Request that their own centre samples be removed/returned from the CCLG Tissue Bank without going through the application process (naturally the monies they had received for registering the samples in the bank would be deducted from their next payment).

In addition, release of local specimens for local research must receive ethics approval for the study.

10.0 Procedure for Release of Material for an Approved Research Project

10.1 Solid Tumours (and non-trial leukaemias)

Once a project has obtained CCLG Biological Studies Steering Group approval and if required, additional REC approval (see section 9.0), the CCLG Tissue Bank Manager/Biological Studies Coordinator will identify suitable specimens. The Tissue Bank Manager/Biological Studies Co-ordinator will then request their release from the CCLG Central Tissue Bank, or from individual centres as appropriate. The researcher will be asked specific questions about the specimens they require for study. Collection of the material is the responsibility of the project researcher who will bear the cost and meet any specific requirements for transportation. Material will be despatched within 1 month of receiving the request. Form C authorising the release of specimens will only be sent out when a study has full approval from the CCLG Biological Studies Steering Group and, if required separate REC approval for the proposed study (see section 9.0). The researcher will be asked to sign a CCLG Material Transfer Agreement.

10.2 Leukaemia (clinical trial patients only)

Once approval has been given, the CCLG Biological Studies Steering Group will notify the researcher, Chair of the NCRI CCL Clinical Study Group Leukaemia Subgroup and the Chair of the Childhood Leukaemia Cell Bank Steering Committee that approval has been given. The latter will inform the Coordinator of the Childhood Leukaemia Cell Bank database, who will notify the researcher where the material is stored, and also the relevant laboratories. The form authorising the release of the material will only be sent when the following documents have been submitted to the Chair of the Childhood Leukaemia Cell Bank Steering Committee:

- copy of approval letter from CCLG Biological Studies Steering Group
- confirmation of additional research ethics committee approval if required
- confirmation that all information linked to the released samples will remain secure
- the release of samples i.e. a single batch or in sequence (details provided)
- copy of signed disclaimer(s) on quality of samples provided to lead applicant

The researcher will meet the costs of collection and release of the samples. The researcher will be asked to sign a Material Transfer Agreement and will be asked to complete a form about the quality of the specimens.

11.0 Quality Control

11.1 Solid Tumours (and non-trial leukaemias)

All researchers receiving frozen tumour material will be required to return Form C reporting the quality of material received and whether it was suitable for their purposes. Researchers who fail to comply with this requirement will not be considered for further access to biological specimens.

Surplus material obtained for biological studies which is not needed for the approved project should be stored by the researcher on behalf of the CCLG for future CCLG approved research, in accordance with HT Act requirements. Where this is not possible it must be returned to the CCLG Central Tissue Bank. This surplus material must not be used for other

local research projects unless these have received approval from the CCLG Biological Studies Steering Group. Researchers must feed back at the end of the study, whether the study was satisfactorily completed. Annual reports will be requested on behalf of the CCLG Biological Studies Steering Group.

11.2 Leukaemia (clinical trial patients only)

The researcher will complete a form reporting on the quality of the samples received. Surplus material must be tabulated and a completed form returned to the Leukaemia Cell Bank Steering Committee. The material should be stored on behalf of the NCRI CCL Clinical Study Group Leukaemia Subgroup, and must not be used for other local research projects unless these have received approval from the CCLG Biological Studies Steering Group and appropriate Ethics Committee approval. The researcher will be expected to provide feedback on the progress of the study in an annual update.

12.0 Publication Policy

All recipients of tissues from the banks are strongly encouraged to publish their results in the scientific/medical literature. Details of publications arising from approved projects must be listed in annual and final reports. The appropriate acknowledgement for the tissue must be incorporated in published papers, as detailed below.

Manuscripts and abstracts involving leukaemia material must be sent simultaneously to the Chairs of the NCRI CCL Clinical Study Group Leukaemia Subgroup and the Childhood Leukaemia Cell Bank Steering Committee, for final approval prior to submission to a conference or journal.

For biological studies on clinical trial cohorts of patients from the CCLG, requiring active input from these respective bodies for analysis of clinical correlates, the wording "on behalf of the Children's Cancer and Leukaemia Group (CCLG)" or "on behalf of the NCRI CCL Clinical Study Group Leukaemia Subgroup" must be placed at the end of the list of authors.

For biological studies requiring lesser input from the CCLG, or where the tissue samples form only part of a greater collection, then the CCLG should be included in the acknowledgements as follows:

"We thank the CCLG Tissue Bank for access to specimens. The CCLG Tissue & Leukaemia Banks are funded by Cancer Research UK and the Leukaemia & Lymphoma Research Fund."

13.0 Management of the CCLG Tissue Bank

The Steering Committees of the CCLG Tissue Bank and Childhood Leukaemia Cell Bank are responsible for overseeing operational issues relating to management of the Banks, and providing clinical governance.

APPENDIX I Parent/Patient Information Sheets and Consent Forms

- Summary information sheet on tissue donation
- Summary Information sheet for patients on tissue donation
- Parent Information Sheet
- Patient/Young adult Information Sheet (age 18+)
- Patient Information Sheet (age 13+)
- Patient Information Sheet (age 8-12)
- Patient Information Sheet (age under 8)
- Parent /Patient Consent Form

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- UNCONTROLLED IF PRINTED

(To be printed on institutional headed paper)

**The Children's Cancer and Leukaemia Group
Tissue Bank (2008 BS 01)
Summary information sheet on consenting to storage and use of
tissue samples for research**
(Version 2.0, 6th April 2011)

The Children's Cancer and Leukaemia Group (CCLG) is an organisation where doctors, nurses, researchers and patients in the UK and Ireland work together to improve the treatment of children with cancer and leukaemia.

In order to improve diagnosis, treatment, and prevention of childhood cancer and leukaemia, researchers need to be able to study cancer cells in small samples of tumour, bone marrow and blood. The CCLG runs a national Tissue Bank where samples of children's cancers and leukaemias are stored for research.

We are asking you to help with this vital research by giving permission for samples from your child's tumour or leukaemia to be stored in the Bank and used for research, both now and in the future. Samples stored in the Bank are small, usually no bigger than a sugar lump for pieces of tumour, or a teaspoon or two of blood or bone marrow.

The CCLG Tissue and Leukaemia Banks do not obtain any samples of tumour or leukaemia just for research. Any samples that are stored in the Bank are those that are "left over" from operations, biopsies or other procedures, after the doctors caring for your child have done everything they need to do with the samples. This means your child will not have anything extra done to them on top of their normal treatment unless we ask you separately about this.

Under the Human Tissue Act 2004, children and young people who are "competent" may consent to storage and use of tissue for research, regardless of their age. A parent may give consent if this is what the child prefers or if there is doubt about whether the child understands enough to give consent. In most cases we will ask parents of children below the age of 18 to consent as well as asking children and young people themselves (if "competent") to consent.

1. If you sign the consent form, you are agreeing that the tissue samples can be stored and used in research projects. Samples will only be used in scientifically and ethically approved studies.
2. You are under no obligation to consent for storage and use of tissue samples in the CCLG Tissue and Leukaemia Banks. 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.
3. You or your child can withdraw consent at any time without having to give a reason. Your child's samples will then be removed from the Bank. Withdrawing consent will not affect the care given to your child in any way.

4. Doctors are not asked to obtain extra material for the CCLG Tissue and Leukaemia Banks when they are carrying out procedures for your child. Most tissue samples stored in the Bank are those “left over” after procedures carried out to diagnose or treat your child’s illness, when there is no further need for the samples for clinical purposes. If extra samples are requested, you would be asked to consent for that separately. Consenting to banking covers storage and use of the samples only.
5. Tissue samples may be stored either at the hospital where your child is being treated or at a national storage centre. The samples are stored securely.
6. To maintain anonymity, the samples are given a code. Researchers who use the samples will not know your child’s name or any other identifiable details. Information such as your child’s diagnosis and treatment is kept so it can be matched up with the tissue, but only in anonymised form. The link between this code and information about your child’s diagnosis and treatment is kept secret, in accordance with the Data Protection Act.
7. In line with normal practice, individual results of research on your child’s samples will not be given to you or your child’s doctors. However, general results of research on tissue samples will be published regularly in CCLG newsletters and/or elsewhere.
8. Your child’s samples could be used in more than one research project, but you will be asked to consent once only for storage and use of the samples for research.
9. Although samples are mostly used by university-based researchers, it is possible that the samples might be used in research by commercial organisations or in commercially-sponsored research, subject to scientific and ethical approval.
10. You and your child would not receive money from any discoveries made from research on tissue samples.
11. If your child is not able to give their consent now, either because they are too young or not yet ‘competent’ to understand the information to be able to give informed consent, we ask you to inform your child when s/he is able to understand that they have tissue stored for research. Your child is very welcome to discuss tissue banking with his/her doctors.

We hope that research using samples from the CCLG Tissue and Leukaemia Banks will help to improve treatment for children with cancer in the future.

Thank you for taking the time to read this sheet.

(To be printed on institutional headed paper)

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

(Version 1.0, 6th April 2011)

The Children's Cancer and Leukaemia Group (CCLG) is an organisation where doctors, nurses, researchers and patients in the UK and Ireland work together to improve the treatment of children with cancer and leukaemia.

In order to improve diagnosis, treatment, and prevention of childhood cancer and leukaemia, researchers need to be able to study cancer cells in small samples of tumour, bone marrow and blood. The CCLG runs a national Tissue Bank where samples of children's cancers and leukaemias are stored for research.

We are asking you to help with this vital research by giving permission for samples from your tumour or leukaemia to be stored in the bank and used for research, both now and in the future. Samples stored in the bank are small, usually no bigger than a sugar lump for pieces of tumour, or a teaspoon or two of blood or bone marrow.

The CCLG Tissue and Leukaemia Bank does not obtain any samples of tumour or leukaemia just for research. Any samples that are stored in the Bank are those that are "left over" from operations, biopsies or other procedures, after the doctors caring for you have done everything they need to do with the samples. This means you will not have anything extra done to you on top of your normal treatment unless we ask you separately about this.

Under the Human Tissue Act 2004, children and young people who are "competent" may consent to storage and use of tissue for research, regardless of their age. A parent may give consent if this is what the child prefers or if there is doubt about whether the child understands enough to give consent. In most cases we will ask parents of children below the age of 18 to consent as well as asking children and young people themselves (if "competent") to consent.

1. If you sign the consent form, you are agreeing that the tissue samples can be stored and used in research projects. Samples will only be used in scientifically and ethically approved studies.
2. You are under no obligation to consent for storage and use of tissue samples in the CCLG Tissue and Leukaemia Bank. If you prefer not to consent, this will not affect the care given to you in any way. Whether or not you decide to give consent, you will still receive the best available treatment.
3. You can withdraw consent at any time without having to give a reason. Your samples will then be removed from the Bank. Withdrawing consent will not affect the care given to you in any way.

4. Doctors are not asked to obtain extra material for the CCLG Tissue and Leukaemia Bank when they are carrying out procedures. Most tissue samples stored in the Bank are those “left over” after procedures carried out to diagnose or treat your illness, when there is no further need for the samples for clinical purposes. If extra samples are requested, you would be asked to consent for that separately. Consenting to banking covers storage and use of the samples only.
5. Tissue samples may be stored either at the hospital where you are being treated or at a national storage centre. The samples are stored securely.
6. To maintain anonymity, the samples are given a code. Researchers who use the samples will not know your name or any other identifiable details. Information such as your diagnosis and treatment is kept so it can be matched up with the tissue, but only in anonymised form. The link between this code and information about your diagnosis and treatment is kept secret, in accordance with the Data Protection Act.
7. In line with normal practice, individual results of research on your samples will not be given to you or your doctors. However, general results of research on tissue samples will be published regularly in CCLG newsletters and/or elsewhere.
8. Your samples could be used in more than one research project, but you will be asked to consent once only for storage and use of the samples for research.
9. Although samples are mostly used by university-based researchers, it is possible that the samples might be used in research by commercial organisations or in commercially-sponsored research, subject to scientific and ethical approval.
10. You would not receive money from any discoveries made from research on your tissue samples.

We hope that research using samples from the CCLG Tissue and Leukaemia Bank will help to improve treatment for children with cancer in the future.

Thank you for taking the time to read this sheet

(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.

(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 PATIENTS AGED 18+

(Version 1.0, 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 organised by members of the Children's Cancer and Leukaemia Group

The children's cancer service in the UK 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 you 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.

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 you.

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 patient 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 name. Researchers are not given any personal information that could identify you.

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

Patients 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.

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.

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

Tissue samples will be 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 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, 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 projects that want to use the samples are suitable.

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 patients who give the samples. However, they do not need to know their 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 Coordinating 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 you, only an anonymous code.

How do I know that my 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 samples?

In line with normal practice, individual results of research on your samples will not be given to you or your doctors. Research tests do not form part of your 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 you, then your 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 you. 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 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 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 you in any way. Whether or not you decide to give consent, you 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 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, Royal Hospital for Children (Bristol), Department of Cellular and Molecular Medicine, School of Medical Sciences, 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 USED IN RESEARCH
WITHOUT YOUR AGREEMENT.**

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(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 PATIENTS AGED 13+

(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 children's 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 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). The samples can be used in scientifically approved research projects. Research on tissue samples may not directly benefit you now, but it may help children and young people with cancer in the future.

What is involved in consenting to tissue banking?

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

Tissue samples stored in the Bank are those "left over" after operations, biopsies or other procedures, when doctors treating patients 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 you.

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

Information about the diagnosis and treatment of the person 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 name. Researchers are not given any personal information that could identify you.

What if extra samples of tissue are wanted?

Patients 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. We will usually ask your parent(s) to consent as well.

Some young people might have trouble taking in or understanding the information about tissue banking, especially if it is a difficult time. Or they might prefer their parent(s) to give consent. In either situation, the parent(s) can give consent. You can decide whether you would like to consent yourself or whether you would like your parent(s) to consent for you.

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

Tissue samples will be 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 released 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 researcher requesting samples has a scientifically 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 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 patients' names or any personal details. To maintain anonymity all samples are given a code.

The link between the code and your 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 you, only an anonymous code.

How do I know that my 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 samples?

In line with normal practice, individual results of research on your samples will not be given to you or your doctors. Research tests do not form part of your 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, then your 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 you. 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 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 family 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 you in any way. Whether or not you decide to give consent, you 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 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, Royal Hospital for Children (Bristol), Department of Cellular and Molecular Medicine, School of Medical Sciences, 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.**

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- UNCONTROLLED IF PRINTED

(To be printed on institutional headed paper)

**Children's Cancer and Leukaemia Group
Tissue Bank (2008 BS 01)
Storing and using blood, bone marrow and tumour samples for
research**

INFORMATION SHEET FOR CHILDREN AGED 8 - 12 YEARS

(Version 3.0, 6th April 2011)

1. Introduction

We would like to ask you if we can keep small samples of your blood, bone marrow and tumour lump (if you have one) to store in a Tissue or Leukaemia Bank, to help with research. It's important that you understand and are happy to let us store and use your samples. You can say no if you want to. If you have any worries or would like to ask any questions, you can ask your doctor or nurse.

2. What is research?

Research is done in order to find out more about something. Your teacher might ask you to do research for a school project. This usually means looking things up in books or on the internet. Medical research on illnesses such as cancer and leukaemia means doing special tests in a laboratory on blood and tumour samples to find out new things.

3. Why is the Tissue and Leukaemia Bank needed?

Doctors and scientists need to do research on small samples from lots of children who have had cancer or leukaemia in the past. This will help us to understand why children like yourself become ill in the first place and help find ways to improve treatment. To make sure we have enough samples to do the research, children and young people with tumour lumps or leukaemia are being asked to consent (give permission) for small samples of their blood, bone marrow/or tumour lump to be kept for research. These samples could be stored for many years and may be used in research done either here at **(local centre name)** or at other hospitals.

4. What will happen if I say 'Yes'?

We are asking you to say 'Yes' or 'No' to the question:

"Can we keep some of your blood and bone marrow/or tumour lump (if you have one) for scientists to do research?"

The samples will mostly be little pieces of tissue left over from when you have operations or biopsies, when the doctors looking after you have finished with them. The only time we would need something extra is when we need an extra blood sample but this sample would be taken at the same time as your treatment so you would not have to have an extra needle or anything else.

5. Do I have to say 'Yes'?

No you don't. It's up to you to decide if you want to give some of your blood, bone marrow and/or tumour lump for research. If you say yes now but change your mind when you're older, just tell your mum or dad or your doctor. Any samples left will be disposed of, usually by burning them. (If you're still under 18 years old at that time, your parents will need to agree).

6. Will it do some good if I say 'Yes'?

We hope the research that can be done using your samples will help us improve treatments for children like yourself in the future.

7. What will happen if I say 'No'?

If you decide to say no, nobody will mind and your treatment will still be the same.

8. What shall I do now?

Take some time to think about whether or not you want to give your samples for research. It would be a good idea to talk with your mum or dad or anyone else you would like to ask, before you decide. Your doctors and nurses would be happy to answer any questions you may have. If you do decide to say 'Yes', you'll be asked to sign a special form. Your mum or dad will also need to sign this form.

My Doctor is:

Telephone Number:

My Nurse is:

Telephone Number:

(To be printed on institutional headed paper)

**Children's Cancer and Leukaemia Group
Tissue Bank (2008 BS 01)**

**INFORMATION SHEET WHICH CAN BE READ TO CHILDREN AGED LESS
THAN 8 YEARS**

(Version 3.0, 6th April 2011)

* Note to the reader: please read the whole sheet before reading this to your child and choose the most appropriate words to use for your child.

** Only use if your child has a tumour lump.

Doctors and scientists want to find out why children get *leukaemia/ a tumour/ a lump and work out how to make better medicines and treatments. They need to do special tests, called research, on small samples from children who are ill with illnesses like yours.

All children with *leukaemia/ a tumour/ a lump are being asked to give a small bit of their blood or bone marrow (**and lump) to be kept a 'tumour bank'. This is like a big piggy-bank, where each coin is a little bit of frozen blood or bone marrow or tumour lump given by a child like you. These have to be kept in a special place until the doctors and scientists need them for research.

The blood and bone marrow and **(bit of the tumour or lump) would only be taken when you are having other tests or an operation, so you would not need any extra needles.

What would you like me to do?

We would like you to allow us to keep a small bit of your blood and bone marrow **(and tumour or lump) for research in the future.

What do I have to do?

We are asking you to say 'Yes' or 'No' to the question "Can we keep some of your blood and bone marrow **(and tumour or lump) for scientists to do research?"

Do I have to say yes?

No. You don't.

What will happen if I say 'No'?

If you say no, nobody will mind and your treatment will still be the same. If you say 'Yes' now but decide when you're older that you don't want your blood and bone marrow **(or tumour/lump) to be used for research, then just tell your doctor. Any samples left will be thrown away.

What shall I do now?

Talk with your mum or dad about what you are being asked to do. The doctors and nurses would also be happy to help you if you would like to talk to them.

*(To be printed on institutional headed paper and attached
to the consent form provided)*



CCLG Tissue Bank Consent
(2008 BS 01)
(v.3.0, 6th April 2011)

Chief Investigator: Dr Keith Brown

Principal Investigator:

Name of Centre:

