

15 MAY 2008



**National Research Ethics Service**  
Trent Research Ethics Committee

Derwent Shared Services  
Laurie House  
Colyear Street  
Derby  
DE1 1LJ

Telephone: 01332 868905  
Facsimile: 01332 868930

14 May 2008

Dr Neil Sebire  
Consultant in Paediatric Pathology  
Great Ormond Street Hospital  
LONDON  
WC1N 3JH

Dear Dr Sebire

**05/MRE04/2 A national protocol for collecting and banking childhood cancer tissue samples for research**

As you know, the content of this study was included in a new submission to Trent REC (**08/H0405/22 – The CCLG Tissue Bank**) in order to comply with the requirements of the Human Tissue Act 2004 and the Human Tissue Regulations.

I write to confirm that this study is now considered withdrawn/void, having been superseded by study 08/H0405/22 – The CCLG Tissue Bank, which was given a favourable opinion by Trent REC on 14 May 2008.

Yours sincerely

Ian Gaywood  
Chairman  
Trent Research Ethics Committee

Copy to: Gavin Whyman, CCLG  
UHL R & D



# National Research Ethics Service

## Trent Research Ethics Committee

Derwent Shared Services  
Laurie House  
Colyear Street  
Derby  
DE1 1LJ

Telephone: 01332 868905

Facsimile: 01332 868930

14 May 2008

Dr Gavin Whyman  
CCLG Biological Studies Co-ordinator  
CCLG  
University of Leicester  
3<sup>rd</sup> Floor, Hearts of Oak House  
9 Princess Road West  
LEICESTER  
LE1 6TH

Dear Gavin

### 08/H0405/22 – The CCLG Tissue Bank

Thank you for your letter of 2 April 2008 enclosing the application for this study, which was considered by Trent REC on 1 May 2008

I am pleased to inform you that the study was given a favourable opinion and a separate letter and conditions of approval are attached. The conditions of approval are based on a standard document which I have amended. Would you please read these carefully to ensure that you agree they clearly reflect the purposes for which banked tissue can be used without additional REC approval.

In response to your queries:

- **Question 1** asked the committee to consider whether requirements for substantial amendment could be limited to changes to the protocol and tissue registration forms, because it was thought that this had been agreed for the current study. However no evidence of this could be found in the study documentation held either by the REC or CCLG. Therefore the committee agreed that any amendments, whether substantial or minor, should be submitted as per REC SOPs (Section 5 refers) which are available at [www.nres.npsa.nhs.uk](http://www.nres.npsa.nhs.uk).
- **Question 2** the committee agreed to your proposal to harmonise annual reporting arrangements so that annual reports can be submitted for all CCLG Biological Studies at the same time (including those approved before the generic approval given for the current study). To facilitate this, would you please provide me with a list of all such studies, their original approval dates and proposed new annual reporting date, so that I can amend our database.
- **Question 3** I am advised that since the Human Tissue Act does not apply in Scotland, this single England, Wales and Northern Ireland application would allow samples to be banked in Scottish centres without a separate application.

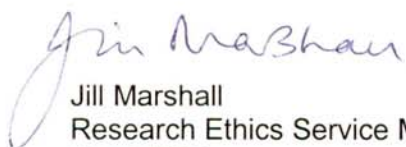
15 MAY 2008

- **Question 4** All Research Tissue Bank applications are automatically site specific exempt – this is reflected in the favourable opinion letter.

The final issue of changed consent arrangements was considered and agreed by the committee, and is covered in the favourable opinion letter.

I hope this is helpful to you.

Kind regards,  
Yours sincerely



Jill Marshall  
Research Ethics Service Manager  
Trent REC

Copy to: Dr Neil Sebire, Chief Investigator



## National Research Ethics Service

### Trent Research Ethics Committee

Derwent Shared Services  
Laurie House  
Colyear Street  
Derby  
DE1 1LJ

Telephone: 01332 868 905  
Amendment/SSI queries 01332 868 842  
Facsimile: 01332 868 930

14 May 2008

Dr Neil Sebire  
Children's Cancer and Leukaemia Group  
University of Leicester  
3rd Floor  
Hearts of Oak House  
9 Princess Road West  
Leicester  
LE1 6TH

Dear Dr Sebire

**Title of the Research Tissue Bank:** The CCLG Tissue Bank  
**REC reference:** 08/H0405/22  
**Designated Individual:** N/A – Virtual Bank – HTA licences held at centres

The Research Ethics Committee reviewed the above application at the meeting held on 01 May 2008, when Gavin Whyman, Biological Studies Co-ordinator, CCLG, attended on your behalf.

#### Ethical issues discussed at the meeting

- 1 The only change from the current study was the proposal to seek combined consent to cover both national and local research. The background to this was that in 2005 when the current study was approved, Trent REC had requested separate consent boxes to allow participants to choose to consent to either local research, national research or both. Since then no patients had selected national research only, and none had selected local research only. Therefore it was proposed to have a single consent, covering both national and local consent. This was agreed.
- 2 Mr Whyman clarified that before the study could proceed at each site, CCLG, as the administrative centre, would require evidence from each participating clinical centre that they met certain conditions, including having a HTA licence. This was accepted.
- 3 Mr Whyman confirmed that reference in the application to animal testing was solely in relation to testing for human disease. This was accepted.

#### Ethical opinion

The members of the Committee present gave a favourable ethical opinion of the above research tissue bank on the basis described in the application form and supporting documentation.

The Committee has also confirmed that the favourable ethical opinion applies to all research projects conducted in the UK using tissue or data supplied by the tissue bank, provided that the release of the tissue or data complies with the attached conditions. It will not be necessary for these researchers to make project-based applications for ethical approval. They will be deemed to have ethical approval from this committee. You should provide the researcher with a copy of this letter as confirmation of this. The Committee should be notified of all projects receiving tissue and data from the tissue bank by means of an annual report.

### Duration of ethical opinion

The favourable opinion is given for a period of five years from the date of this letter and provided that you comply with the conditions set out in the attached document. You are advised to study the conditions carefully. The opinion may be renewed for a further period of up to five years on receipt of a fresh application. It is suggested that the fresh application is made 3-6 months before the 5 years expires, to ensure continuous approval for the research tissue bank.

### Approved documents

The documents reviewed and approved at the meeting were:

<i>Document</i>	<i>Version</i>	<i>Date</i>
Application	ab/105883/1	10 April 2008
Covering Letter		02 April 2008
Participant Information Sheet: Summary Information Sheet	V 1.0	01 April 2008
Participant Information Sheet: Aged Under 8	V 1.0	01 April 2008
Participant Information Sheet: Aged 8 - 12	V 1.0	01 April 2008
Participant Information Sheet: Aged 13 +	V 1.0	01 April 2008
Participant Information Sheet: Parents	V 1.0	01 April 2008
Single Participant Consent Form: Patients and Parents/Guardian	V 1.0	01 April 2008
Form B - Constitutional DNA Registration Form	V 1.0	01 April 2008
Form A - Tissue Registration Form	V 1.0	01 April 2008
protocol for Management of the Tissue Bank	V1.0	01 April 2008
Guidelines for Reviewers	V 1.0	01 April 2008
Guidelines for Applicants	V 1.0	01 April 2008
Application for CCLG Biological Study	V 1.0	01 April 2008

### Licence from the Human Tissue Authority

It is noted that the CCLG Tissue Bank is a 'virtual' bank and as such cannot hold a Human Tissue Authority licence.

All participating tissue banks must therefore obtain a licence from the Human Tissue Authority for the storage and use of human tissue for research purposes. However there is no need to provide this Committee with a copy of each licence.

### Replacement of existing approved study

As you know, this study was submitted in order to comply with requirements imposed by the Human Tissue Act 2004 and the Human Tissue Regulations, and will replace Trent REC approved study 05/MRE04/2. A national protocol for collecting and banking childhood cancer tissue samples for research. **Study 05/MRE04/2 will therefore become void from**

**the date of this approval letter.** A separate letter is enclosed confirming withdrawal of this study.

### **Research governance approval**

A copy of this letter is being sent to the R&D office relating to CCLG (University Hospitals of Leicester R & D Department).

Local research collaborators at other organisations planning to collect tissue or data and supply to the tissue bank will normally require management permission from their organisations. You should advise local collaborators to notify their R&D office and check their approval requirements.

Site-specific assessment (SSA) is not a requirement for ethical review of research tissue banks. There is no need to inform Local Research Ethics Committees.

### **Membership of the Committee**

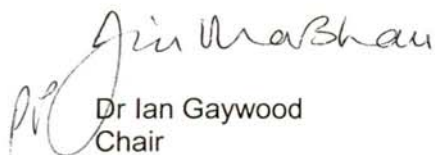
The members of the Ethics Committee who were present at the meeting are listed on the attached sheet.

### **Statement of compliance**

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees (July 2001) and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

08/H0405/22	Please quote this number on all correspondence
-------------	--

Yours sincerely

  
Dr Ian Gaywood  
Chair

E-mail: [jill.marshall@derwentsharedservices.nhs.uk](mailto:jill.marshall@derwentsharedservices.nhs.uk)

*Enclosures: List of names and professions of members who were present at the meeting and those who submitted written comments*

*Standard approval conditions [SL-AC3]*

*Copy to: Dr Gavin Whyman, CCLG  
UHL R & D Department*

### CONDITIONS OF ETHICAL APPROVAL

Research Ethics Committee:	Trent
Research Tissue Bank:	The CCLG Tissue Bank
REC reference number:	08/H0405/22
Name of applicant:	Dr Neil Sebire
Date of approval:	14 May 2008

Ethical approval is given to the Research Tissue Bank ("the Bank") by the Research Ethics Committee ("the Committee") subject to the following conditions.

1. Further communications with the Committee

1.1 Further communications with the Committee are the personal responsibility of the applicant.

2. Duration of approval

2.1 Approval is given for a period of 5 years, which may be renewed on consideration of a new application by the Committee, taking account of developments in legislation, policy and guidance in the interim. New applications should include relevant changes of policy or practice made by the Bank since the original approval together with any proposed new developments.

3. Licensing

3.1 It is appreciated that as a virtual bank, CCLG cannot hold a Human Tissue Licence. However a copy of the Licence from the Human Tissue Authority (HTA) for each participating centre should be held by CCLG.

3.2 The Committee should be notified of any revocation of a Licence or failure to obtain renewal. If any of the Licences are revoked, ethical approval would be terminated for that centre. Any other significant developments that might affect ethical approval, such as changes in licensing conditions, should also be notified.

#### 4. Generic ethical approval for projects receiving tissue

- 4.1 Samples of human tissue or other biological material may be supplied and used in research projects to be conducted by researchers and research institutions external to the Bank within the UK in accordance with the following conditions, as well as meeting the criteria set out in Section 9.0 of the Protocol.
- 4.1.1 The research project should be within the fields of medical or biomedical research described in the approved application form and Section 9.0 of the Protocol.
- 4.1.2 The Bank should be satisfied that the research has been subject to scientific critique, is appropriately designed in relation to its objectives and (with the exception of student research below doctoral level) is likely to add something useful to existing knowledge.
- 4.1.3 Where tissue samples have been donated with informed consent for use in future research ("broad consent"), the Bank should be satisfied that the use of the samples complies with the terms of the donor consent.
- 4.1.4 All samples and any associated clinical information must be non-identifiable to the researcher at the point of release (i.e. anonymised or linked anonymised).
- 4.1.5 Samples will not be released to any project requiring further data or tissue from donors or involving any other research procedures. Any contact with donors must be confined to ethically approved arrangements for the feedback of clinically significant information.
- 4.1.6 A supply agreement must be in place with the researcher to ensure storage, use and disposal of the samples in accordance with the HTA Codes of Practice, the terms of the ethical approval and any other conditions required by the Bank.
- 4.2 A research project in the UK using tissue provided by a Bank in accordance with these conditions will be considered to have ethical approval from the Committee under the terms of this approval. In England, Wales and Northern Ireland this means that the researcher will not require a licence from the Human Tissue Authority for storage of the tissue for use in relation to this project.
- 4.3 The Bank may require any researcher to seek specific ethical approval for their project. Such applications should normally be made to the Committee and booked via the COREC Central Allocation System.
- 4.4 A Notice of Amendment form should be submitted to seek the Committee's agreement to change the conditions of generic approval.

#### 5. Records

- 5.1 The Bank should maintain a record of all research projects to which tissue has been supplied. The record should contain at least the full title of the project, a summary of its purpose, the name of the Chief Investigator, the sponsor, the location of the research, the date on which the project was approved by the Bank, details of the tissue released and any relevant reference numbers.
- 5.2 The Committee may request access to these records at any time.

## 6. Annual reports

- 6.1 An annual report should be provided to the Committee listing all projects for which tissue has been released in the previous year. The list should give the full title of each project, the name of the Chief Investigator, the sponsor, the location of the research and the date of approval by the Bank. The report is due on the anniversary of the date on which ethical approval for the Bank was given.
- 6.2 The Committee may request additional reports on the management of the Bank at any time.

## 7. Substantial amendments

- 7.1 Substantial amendments should be notified to the Committee and ethical approval sought before implementing the amendment. A substantial amendment generally means any significant change to the arrangements for the management of the Bank as described in the application to the Committee and supporting documentation.
- 7.2 The NRES Notice of Amendment form should be used to seek approval. The form is available at <http://www.corec.org.uk/applicants/apply/amendments.htm#other>.
- 7.3 The following changes should always be notified as substantial amendments:
- 7.3.1 Any significant change to the policy for use of the tissue in research, including changes to the types of research to be undertaken or supported by the Bank.
- 7.3.2 Any significant change to the types of biological material to be collected and stored, or the circumstances of collection.
- 7.3.3 Any significant change to informed consent arrangements, including new/modified information sheets and consent forms.
- 7.3.4 A change to the conditions of generic approval (omit if not applicable).
- 7.3.5 Any other significant change to the governance of the RTB.

## 8. Serious adverse events

- 8.1 The Committee should be notified as soon as possible of any serious adverse event or reaction, any serious breach of security or confidentiality, or any other incident that could undermine public confidence in the ethical management of the tissue. The criteria for notifying the Committee will be the same as those for notifying the Human Tissue Authority in the case of research tissue banks in England, Wales and Northern Ireland.

## 9. Other information to be notified

- 9.1 The Committee should be notified of any change in the contact details for the applicant or where the applicant hands over responsibility for communication with the Committee to another person at the establishment.

10. Closure of the Bank

- 10.1 Any plans to close the Bank should be notified to the Committee as early as possible and at least two months before closure. The Committee should be informed what arrangements are to be made for disposal of the tissue or transfer to another research tissue bank.
- 10.2 Where tissue is transferred to another research tissue bank, the ethical approval for the Bank is not transferable. Where the second bank is ethically approved, it should notify the responsible Research Ethics Committee. The terms of its own ethical approval would apply to any tissue it receives.

11. Breaches of approval conditions

- 11.1 The Committee should be notified as soon as possible of any breach of these approval conditions.
- 11.2 Where serious breaches occur, the Committee may review its ethical approval and may, exceptionally, suspend or terminate the approval.