



## Health Research Authority

### NRES Committee North East - Newcastle & North Tyneside 1

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Telephone: 0191 428 3565

4 September 2013

Professor Stephen C Robson  
Institute of Cellular Medicine  
3rd Floor, Leazes Wing, Medical School  
Newcastle University  
Newcastle upon Tyne  
NE2 4HH

Dear Professor Robson

**Title of the Research Tissue Bank:** Human Developmental Biology Resource  
**REC reference:** 08/H0906/21+5  
**Designated Individual:** Professor Andy Hall  
**IRAS project ID:** 119798

Thank you for your letter of 30 August 2013, responding to the Committee's request for further information on the above research tissue bank and submitting revised documentation.

The further information has been considered on behalf of the Committee by the Chair.

We plan to publish your research summary wording for the above study on the NRES website, together with your contact details, unless you expressly withhold permission to do so. Publication will be no earlier than three months from the date of this favourable opinion letter. Should you wish to provide a substitute contact point, require further information, or wish to withhold permission to publish, please contact the Co-ordinator Gillian Mayer, [nrescommittee.northeast-newcastleandnorthtyneside1@nhs.net](mailto:nrescommittee.northeast-newcastleandnorthtyneside1@nhs.net)

#### Confirmation of ethical opinion

On behalf of the Committee, I am pleased to confirm a **Favourable** ethical opinion of the above research tissue bank on the basis described in the application form and supporting documentation as revised.

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 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 this 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 standard conditions of ethical approval for Research

Tissue Banks 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>
Human Tissue Authority Licence		22 June 2011
Other: SOPs for Recruitment	1.0	14 June 2013
Other: Summary of Research Programmes		
Other: Wellcome Trust Foundation confirmation/Sponsor confirmation email		
REC application	(IRAS 3.5)	14 June 2013
<i>Response to Request for Further Information</i>	S Robson	30 August 2013
Participant Consent Form: (+ copy with tracked changes)	2	29 August 2013
Participant Information Sheet: (+ copy with tracked changes)	2	29 August 2013
Protocol for Management of the Tissue Bank	2.0 (plus copy with track changes)	28 August 2013

## Licence from the Human Tissue Authority

Thank you for providing a copy of the above licence.

## Research governance

Under the Research Governance Framework (RGF), there is no requirement for NHS research permission for the establishment of research tissue banks in the NHS. Applications to NHS R&D offices through IRAS are not required as all NHS organisations are expected to have included management review in the process of establishing the research tissue bank.

Research permission is also not required by collaborators at tissue collection centres (TCCs) who provide tissue or data under the terms of a supply agreement between the organisation and the research tissue bank. TCCs are not research sites for the purposes of the RGF.

Research tissue bank managers are advised to provide R&D offices at all TCCs with a copy of the REC application for information, together with a copy of the favourable opinion letter when available. All TCCs should be listed in Part C of the REC application.

NHS researchers undertaking specific research projects using tissue or data supplied by a research tissue bank must apply for permission to R&D offices at all organisations where the research is conducted, whether or not the research tissue bank has ethical approval.

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.

## Statement of compliance

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

## After ethical review

Now that you have completed the application process please visit the National Research Ethics Service website > After Review

Here you will find links to the following:

- a) Providing feedback. You are invited to give your view of the service that you have received from the National Research Ethics Service and the application procedure. If you wish to make your views known please use the feedback form available on the website.
- b) Annual Reports. Please refer to the attached conditions of approval.
- c) Amendments. Please refer to the attached conditions of approval.

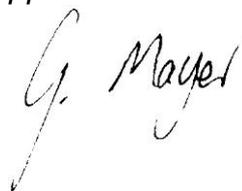
We are pleased to welcome researchers and R & D staff at our NRES committee members' training days – see details at <http://www.hra.nhs.uk/hra-training/>

08/H0906/21+5

Please quote this number on all correspondence

Yours sincerely

pp



**Professor Philip Preshaw**  
Chair

E-mail: nrescommittee.northeast-newcastleandnorthtyneside1@nhs.net

Enclosures: *Standard approval conditions for Research Tissue Banks*

Copy to: *Professor Andy Hall - Northern Institute for Cancer Research,  
Newcastle University*

## CONDITIONS OF ETHICAL APPROVAL

Research Ethics Committee:	NRES Committee North East - Newcastle & North Tyneside 1
Research Tissue Bank:	Human Developmental Biology Resource
REC reference number:	08/H0906/21+5
Name of applicant:	Professor Stephen Robson
Date of approval:	04 September 2013
IRAS project ID:	119798

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 A copy of the Licence from the Human Tissue Authority (HTA) should be provided when available (if not already submitted).

3.2 The Committee should be notified if the Authority renews the licence, varies the licensing conditions or revokes the Licence, or of any change of Designated Individual. If the Licence is revoked, ethical approval would be terminated.

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 within the establishment responsible for the Bank and/or by researchers and research institutions external to the Bank within the UK and in other countries in accordance with the following conditions.

- 4.1.1 The research project should be within the fields of medical or biomedical research described in the approved application form.
- 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.

## 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

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.

The NRES Notice of Amendment form should be used to seek approval. The form is available at <http://www.nres.npsa.nhs.uk/applicants/after-ethical-review/amendments/#Noticesofsubstantialamendment>.

- 7.1 The following changes should always be notified as substantial amendments:
- 7.1.1 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.
  - 7.1.2 Any significant change to the types of biological material to be collected and stored, or the circumstances of collection.
  - 7.1.3 Any significant change to informed consent arrangements, including new/modified information sheets and consent forms.
  - 7.1.4 A change to the conditions of generic approval ([omit if not applicable](#)).
  - 7.1.5 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.