NHS
Health Research Authority

National Research Ethics Service

NRES Committee London - Fulham
HRA NRES Centre Manchester
Barlow House
3rd Floor, 4 Minshull Street
Manchester
M1 3DZ

Telephone: 0161 625 7821
Facsimile: 0161 625 7299

23 July 2013

Professor A J Copp
UCL
Institute of Child Health UCL,
30 Guilford Street
London
WC1N 1EH

Dear Professor Copp

Title of the Research Tissue Bank:	**The Human Developmental Biology Resource**
REC reference:	**08/H0712/34+5**
Designated Individual:	**Professor A J Copp**
IRAS project ID:	**134561**

The Research Ethics Committee reviewed the above application at the meeting held on 15 July 2013. The Committee welcomed Dr Diane Gerrilli to the meeting.

1. The Committee asked for clarification on the process of obtaining consent from individuals and the transfer of samples. Dr Gerrilli clarified that all material is sourced from terminations of pregnancy. The patient will go to see the doctor and counsellor and then sign the appropriate form. At this stage they will point out that this research is being undertaken and they will ask if they will be interested in taking part in the study. If they agree, a member of the team who is not directly involved in the clinical care of the patient will approach them. They will be provided with an information sheet and consent form and given time to think about it. If they agree they will provide their material as a gift. The people who handle the material will not have any dealing with the participants. The container in which the sample is stored is packaged securely and given to a courier, who has a service level agreement with UCL and the HTA, and it will then be handed to the laboratory. All the data is put onto database. Dr Gerrilli made reference to a steering group which meets every 6 months to oversee all aspects of the HDBR's management and operation.

2. Dr Gerrilli clarified that they have not had any involvement with the HFEA (Human Fertilisation Embryo Authority).

Dr Gerrilli was thanked for attending and left the meeting room.

The Committee considered the researcher's responses.

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 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.

Additional conditions of approval

In addition to the standard conditions attached, ethical approval is subject to the following:

1. Please state revise the Information Sheet as follows;
    i. State what the acronym bpas stands for. This also applies to other supporting documents which contain the bpas logo.
    ii. There is an outdated link at the bottom of the Information Sheets which no longer exists. The current link is http://www.nres.nhs.uk/applications/guidance/ Please update the information sheets to reflect this.
2. Please revise the Consent Form as follows;
    i. Include the following standard mandatory statement 'I understand that relevant data collected during the study, may be looked at by individuals from [*company name*], from regulatory authorities or from the NHS Trust, where it is relevant to my taking part in this research. I give permission for these individuals to have access to this data.'
    ii. Replace the 'yes/no' option with boxes to initial.

Approved documents

The documents reviewed and approved at the meeting were:

Document	*Version*	*Date*
Covering Letter		14 June 2013
Human Tissue Authority Licence	12220	01 January 2013
Other: bpas sign out sheet	3	01 December 2011
Other: KCH sign out sheet	5	01 December 2011
Other: UCLH sign out sheet	4	01 December 2011
Other: bpas consent SOP	4	01 December 2011
Other: KCH consent SOP	6	01 December 2011
Other: UCLH consent SOP	5	01 December 2011
Other: bpas consent SOP	4	01 December 2011
Other: KCH collection SOP	6	01 December 2011
Other: UCLH collection SOP	5	01 December 2011
Other: Andre Copp Short CV		12 June 2013
Other: Amendment AM03		12 January 2012

Other: HDBR Registration Form	8	01 May 2013
Participant Consent Form: bpas	7	01 December 2011
Participant Consent Form: KCH	9	01 December 2011
Participant Consent Form: UCLH		01 December 2011
Participant Information Sheet: bpas	6	01 December 2011
Participant Information Sheet: KCH	8	01 December 2011
Participant Information Sheet: UCLH	7	01 December 2011
Protocol for Management of the Tissue Bank	6	01 December 2011
REC application	3.5	12 June 2013

Licence from the Human Tissue Authority

Thank you for providing a copy of the above licence.

Research governance

A copy of this letter is being sent to the R&D office responsible for University College London Hospitals.

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 the 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.

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 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/H0712/34+5	**Please quote this number on all correspondence**

Yours sincerely

Signed on behalf of:
Dr Charles Mackworth-Young
Chairman

E-mail: nrescommittee.london-fulham@nhs.net

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

Standard approval conditions

Copy to: David Wilson, University College London

Dr Dianne Gerrelli, HDBR Resource Manager

NRES Committee London - Fulham

Attendance at Committee meeting on 15 July 2013

Committee Members:

Name	*Profession*	*Present*	*Notes*
Prof Alison Crombie	Anthropologist Nurse	Yes	
Dr Kanagasabai Ganeshaguru	Retired Scientist	Yes	
Dr Shaun Griffin	Director of Communications and Public Affairs – Human Tissue Authority	No	
The Rev'd Nigel Griffin	Hospital Chaplain	No	
Dr Akil Jackson	Physician	Yes	
Mr David Leonard	Pharmacist	Yes	
Dr Charles Mackworth-Young	Physician (Chairman)	Yes	
Dr Colin Michie	Paediatrician	Yes	
Dr Frank Miskelly	Physician (Vice-Chairman)	Yes	
Dr Shirlony Morgan	Psychiatrist	Yes	
Professor Sandra Oliver	Retired Organisational Psychologist	No	
Lady Alexandra Roche	Lay Member	Yes	
Mrs Gillian Sichau	Occupational Therapist	Yes	
Mrs Katie Wilkinson	Clinical Trials Centre Manager	Yes	
Mrs Margaret Anne Williams	Lay Member	No	
Dr Ruth Williamson	Radiologist	Yes	

Also in attendance:

Name	*Position (or reason for attending)*
Mr Noel Graham	Centre Manager - HRA NRES Centre Manchester
Miss Shehnaz Ishaq	Committee Co-ordinator
Ms Monsey McLeod	Pharmacist
Mrs Ann Tunley	Regional Manager (North)

Written comments received from:

Name	*Position*
Dr Shaun Griffin	Director of Communications and Public Affairs – Human Tissue Authority

Health Research Authority

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3rd Floor, 4 Minshull Street
Manchester
M1 3DZ

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19 September 2013
REVISED 02 October 2013

Professor A J Copp
UCL
Institute of Child Health UCL,
30 Guilford Street
London
WC1N 1EH

Dear Professor Copp

Title of the Database: **The Human Developmental Biology Resource**
Designated Individual: **Professor A J Copp**
REC reference: **08/H0712/34+5**
IRAS project ID: **134561**

Thank you for your email of 11 September 2013. I can confirm the REC has received the documents listed below and that these comply with the approval conditions detailed in our letter dated 23 July 2013.

Documents received

The documents received were as follows:

Document	*Version*	*Date*
Other: bpas sign out sheet	4	05 August 2013
Other: KCH sign out sheet	6	05 August 2013
Other: UCLH sign out sheet	5	05 August 2013
Other: bpas collection SOP	5	05 August 2013
Other: UCLH collection SOP	6	05 August 2013
Other: bpas consent SOP	5	05 August 2013
Other: UCLH consent SOP	6	05 August 2013
Participant Consent Form: bpas	8	05 August 2013
Participant Consent Form: KCH	10	05 August 2013
Participant Consent Form: UCLH	9	05 August 2013
Participant Information Sheet: KCH	9	05 August 2013
Participant Information Sheet: UCLH	8	05 August 2013
Participant Information Sheet: bpas	8	26 August 2013

Approved documents

The final list of approved documentation for the study is therefore as follows:

Document	*Version*	*Date*
Covering Letter		14 June 2013
Human Tissue Authority Licence	12220	01 January 2013
Other: KCH consent SOP	6	01 December 2011
Other: KCH collection SOP	6	01 December 2011
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08/H0712/34+5	**Please quote this number on all correspondence**

Yours sincerely

Miss Shehnaz Ishaq
Committee Co-ordinator

E-mail: nrescommittee.london-fulham@nhs.net

Copy to: David Wilson, University College London

Dr Dianne Gerrelli, HDBR Resource Manager