Health Research Authority
London - Fulham Research Ethics Committee
Barlow House
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Manchester
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Telephone: 0207 104 8021

01 June 2018

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, amendment 2018-22**
REC reference:	**18/LO/0822**
Designated Individual:	**Professor A J Copp**
IRAS project ID:	**244325**

The Research Ethics Committee reviewed the above application at the meeting held on 21 May 2018. Thank you for attending to discuss the application.

We plan to publish your research summary wording for the Research Tissue Bank on the HRA website, together with your contact details. Publication will be no earlier than three months from the date of this favourable opinion letter. The expectation is that this information will be published for all Research Tissue Banks that receive an ethical opinion but should you wish to provide a substitute contact point, wish to make a request to defer, or require further information, please contact hra.studyregistration@nhs.net outlining the reasons for your request. Under very limited circumstances (e.g. for student research which has received an unfavourable opinion), it may be possible to grant an exemption to the publication of the research summary for the tissue bank

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, subject to the conditions specified below.

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.

This application was for the renewal of a Research Tissue Bank application. The previous REC Reference number for this application was 08/H0712/34+5.

Conditions of the favourable opinion

The favourable opinion is subject to the following conditions being met prior to the start of the Research Tissue Bank.

1. The Committee would be happy to give generic approval but require any studies which would use fetal tissue samples over 23 weeks to make a separate application to REC.
2. Please amend the information sheet to make it clearer that samples may be used in animal research.
3. Please amend the information sheet to include who the mobile number at the end of the document belongs to.
4. Please amend the consent form to make it clearer that the questionnaire/saliva donation was optional.

You should notify the REC once all conditions have been met (except for site approvals from host organisations) and provide copies of any revised documentation with updated version numbers. Revised documents should be submitted to the REC electronically from IRAS. The REC will acknowledge receipt and provide a final list of the approved documentation for the Research Tissue Bank, which can be made available to host organisations to facilitate their permission for the Research Tissue Bank. Failure to provide the final versions to the REC may cause delay in obtaining permissions.

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 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.

Registration of Research Tissue Banks

It is a condition of the ethical approval that all Research Tissue Banks are registered on the UK Clinical Research Collaboration (UKCRC) Tissue Directory. The Research Tissue Bank should be registered no later than 6 weeks after the date of this favourable ethical opinion letter or 6 weeks after the Research Tissue Bank holds tissue with the intention to provide for research purposes. Please use the following link to register the Research Tissue Bank on the UKCRC Directory: https://directory.biobankinguk.org/Register/Biobank Registration is defined as having added details of the types of tissue samples held in the tissue bank.

There is no requirement to separately notify the REC but you should do so at the earliest opportunity e.g. when submitting an amendment or when submitting an annual progress report. We will monitor the registration details as part of the annual progress reporting process.

Summary of discussion at the meeting

Other ethical issues were raised and resolved in preliminary discussion before your attendance at the meeting.

Ethical issues raised by the Committee in private discussion, together with responses given by the researcher when invited into the meeting

The Chair welcomed you and Dr Dianne Gerrelli to the meeting and thanked you for attending to discuss the study.

Social or scientific value; scientific design and conduct of the study

The Committee noted that the renewal included that the HDBR had taken over samples following closure of the fetal pathology department of University College London Hospitals NHS Foundation Trust (UCLH). All samples were taken and stored with consent. The Committee queried if the samples were from a tissue bank or pathology archive. You explained that the samples were from a pathology archive. The Committee were satisfied with the response.

Favourable risk benefit ratio; anticipated benefit/risks for research participants (present and future)

The Committee queried about cell lines. You explained that users of the tissue may use tissue to develop cell lines.

The Committee noted that this would be an emotional time for the women whose consent was being sought and queried what support would be provided. Dr Gerrelli explained that the clinics offer counselling as part of their standard of care and would require the both a counsellor and clinician to approve the termination. Dr Gerrelli explained that they would not approach any women for consent until both signatures are in place.

The Committee were satisfied with the responses.

Care and protection of research participants; respect for potential and enrolled participants' welfare and dignity

The Committee noted that the bank collected fetal tissue aged 4-23 weeks of gestation however some of the material included in the UCLH Fetal Archive was above the current age limit for ongoing HDBR collection (23 weeks gestation). The Committee queried if samples post 23 weeks would be valuable. You explained that these samples were important as a lot of brain development happens within 20 to 24 weeks. The Committee requested that a separate ethics application should be made by the researchers for the use of those samples over 23 weeks gestation.

Informed consent process and the adequacy and completeness of participant information

The Committee discussed the consent for the UCLH Fetal Archive and noted from the application that it stated that consent was in place for most samples and that there were 3 categories. The Committee's main concern was the tissue collected after 1st September 2006. The Committee queried with the researchers the nature of previous consent or lack thereof. Dr Gerrelli explained that they had conducted an audit which confirmed that where the electronic record indicates consent was obtained for tissue usage in research, the signed consent form could indeed be found in the patient notes. Dr Gerrelli explained however that they soon would not have access to these original records. The Committee queried if the HTA were aware of the plans to move the samples. You explained that they had no discussion with the HTA. You explained that under the HTA regulations the tissue had to be stored at a HTA licenced premises which they were. If approval was then granted the samples would be incorporated into

the bank. The Committee queried if they would be inspected by the HTA. You explained that they would. Dr Gerrelli explained that a question they have was to whether to still keep the link to the medical records or completely anonymise the samples and break the linkage. The Committee explained that the bank would have to be compliant with the Human Tissue Act and they could advise.

The Committee noted some corrections for the information sheet and consent form as detailed below.

Other general comments

The Committee queried if there were any further plans for the website. You explained further plans and what it meant about studies being described as “on hold”. The Committee were satisfied with the response.

Please contact the REC Manager if you feel that the above summary is not an accurate reflection of the discussion at the meeting.

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.

Research Tissue Bank Renewals

The Research Tissue Bank has been renewed for a further five years from the end of the previous five year period. The previous five year period ran 23/07/2013 to 23/07/2018.This Research Tissue Bank may be renewed for further periods of five years at a time by following the process described in the above paragraph.

Approved documents

The documents reviewed and approved at the meeting were:

Document	*Version*	*Date*
Covering letter on headed paper [covering letter]		12 April 2018
Human Tissue Authority licence [Licence]		02 January 2013
IRAS Checklist XML [Checklist_19042018]		19 April 2018
Other [CV of PI]		01 April 2018
Other [Registration document for the bank]		30 May 2017
Other [SOP]	6	07 October 2016
Other [SOP]	7	07 October 2016
Other [SOP]	1	23 June 2017
Other [Questionnaire]	2	20 March 2017
Other [Sign out sheet]	7	12 April 2018
Other [Survey]	1	03 May 2017
Participant consent form [Consent form]	14	12 April 2018
Participant information sheet (PIS) [PIS]	14	12 April 2018
Protocol for management of the tissue bank [Protocol]	8	02 April 2018
REC Application Form [RTB_Form_19042018]		19 April 2018

Relative consent form [consent form]	14	12 April 2018
Relative information sheet [PIS]	14	12 April 2018
Summary of research programme(s) [Annual report]		13 July 2017
Summary of research programme(s) [Annual report]		13 July 2017
Summary of research programme(s) [Annual report]		13 July 2017

Licence from the Human Tissue Authority

Thank you for providing a copy of the above licence.

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

Reporting requirements

The attached standard conditions give detailed guidance on reporting requirements for research tissue banks with a favourable opinion, including:

- Notifying substantial amendments
- Submitting Annual Progress reports

The HRA website also provides guidance on these topics, which is updated in the light of changes in reporting requirements or procedures.

User Feedback

The Health Research Authority is continually striving to provide a high quality service to all applicants and sponsors. You are invited to give your view of the service you have received and the application procedure. If you wish to make your views known please use the feedback form available on the HRA website: http://www.hra.nhs.uk/about-the-hra/governance/quality-assurance/

HRA Training

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

18/LO/0822	**Please quote this number on all correspondence**

Yours sincerely

pp

The Rev'd Nigel Griffin
Chair
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:	*Professor A J Copp, UCL*

London - Fulham Research Ethics Committee

Attendance at Committee meeting on 21 May 2018

Committee Members:

Name	*Profession*	*Present*	*Notes*
Mr Keith Berelowitz	Director of Operations Richmond Pharmacology	Yes	
Dr Anthony Farrant	Lecturer in Healthcare Law and Ethics	Yes	
Dr Shaun Griffin	Communications Manager	Yes	
The Rev'd Nigel Griffin (Chair)	Parish Priest	Yes	
Ms Lesley Honeyfield	Research Radiographer	Yes	
Dr Mays Jawad	Research Governance Operations Manager	No	
Mr Greg Kyle-Langley	Private Banker	No	
Dr Monsey McLeod	Pharmacist	Yes	
Dr Frank Miskelly	Physician	Yes	
Mrs Elizabeth Reeves	Clinical Trials Training Executive	Yes	
Mrs Gillian Sichau	Retired Occupational Therapist	Yes	
Miss Onyinyechi Uwasomba	Medical Technologist	Yes	
Mrs Marney Williams	Teacher	Yes	

Also in attendance:

Name	*Position (or reason for attending)*
Miss Anna Bannister	REC Manager