



Health Research Authority

East of England - Cambridge East Research Ethics Committee

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07 March 2023

Dr Cheryl Gillett
Guy's and St Thomas's NHS Foundation Trust
Innovation Hub, Guy's Cancer Centre
Guy's Hospital
Great Maze Pond, London
SE1 9RT

Dear Dr Gillett

Title of the Research Tissue Bank: KHP Cancer Biobank
REC reference: 23/EE/0005
Designated Individual: Dr Cheryl Gillett
IRAS project ID: 323474

Thank you for your letter of 6th March 2023, 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 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 Tissue Bank.

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.

This application was for the renewal of a Research Tissue Bank application. The previous REC Reference number for this application was 18/EE/0025

Recommendation

The Committee recommends that in the future the text of initial invitation messages to be sent to potential participants is separated from the protocol for ease of processing non-substantial amendments to the wording, minimising the need for new protocol versions.

Duration of ethical opinion

The favourable opinion has been renewed for five years from the end of the previous five year period 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 previous five year period ran from 7th February 2018 to 7th February 2023. 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:

<i>Document</i>	<i>Version</i>	<i>Date</i>
Covering letter on headed paper		25 November 2022
Covering letter on headed paper	2	02 February 2023
Human Tissue Authority licence		10 August 2017
IRAS Checklist XML [Checklist_06032023]		06 March 2023
Other [Current approved consent form to highlight that new form updates are primarily related to layout rather than content.]	4.1	03 September 2020
Other [CV]		22 November 2022
Other [Annual progress report 2021-22]		11 February 2022
Other [Biobank applications 2020-21]		11 February 2022
Other [Response to REC]	1	02 February 2023

Other [Response to REC 06-03-23]	2	06 March 2023
Other [23-EE-0005 KHP Cancer Biobank Protocol v6.2]	6.2	06 March 2023
Participant consent form	5.1	01 February 2023
Participant information sheet (PIS)	5.1	01 February 2023
REC Application Form [RTB_Form_25112022]		25 November 2022

Licence from the Human Tissue Authority

Thank you for providing a copy of the above licence.

Tissue banks must obtain a licence from the Human Tissue Authority for the storage and use of human tissue for research purposes. Please provide the Committee with a copy of the licence once it is available.

Research governance

You are advised to check the requirements for approval of the research tissue bank with your R&D office.

Under the UK Policy Framework for Health and Social Care Research 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.

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 annual progress report form. We will monitor the registration details as part of the annual progress reporting process.

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 Learning

We are pleased to welcome researchers and research staff to our HRA Learning Events and online learning opportunities– see details at: <https://www.hra.nhs.uk/planning-and-improving-research/learning/>

23/EE/0005

Please quote this number on all correspondence

Yours sincerely

Dr Alan Lamont

Chair

Pp. Laura Fairman

Approvals Administrator

E-mail: CambridgeEast.REC@hra.nhs.uk

Enclosures: Standard approval conditions

Research Tissue Bank – Conditions of Approval

Copy to: Dr Cheryl Gillett, Guy's and St Thomas's NHS Foundation Trust