CONDITIONS OF REC FAVOURABLE OPINION

Research Ethics Committee:	East of England - Cambridge East Research Ethics Committee
Research Tissue Bank:	KHP Cancer Biobank
REC reference number:	23/EE/0005
Name of applicant:	Dr Cheryl Gillett
Date of approval:	07 March 2023
IRAS project ID:	323474

A REC Favourable Opinion has been given to the Research Tissue Bank ("RTB") 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 RTB, including any substantial amendments approved, 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, the REC favourable opinion would be terminated.

3.3 It is a condition of the REC favourable opinion that all Research Tissue Banks are registered on the UK Clinical Research Collaboration (UKCRC) Tissue Directory

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 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 RTB 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 RTB 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 RTB.

4.2 A research project in the UK using tissue provided by a RTB 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 RTB may require any researcher to seek specific ethical review for their project. Where this applies an application should be prepared and submitted for ethical review.

4.4 A substantial amendment 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 RTB, 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 RTB. The report is due on the anniversary of the date on which ethical approval for the RTB was given.

6.2 The Committee may request additional reports on the management of the RTB at any time.

7. Substantial amendments

7.1 Substantial amendments should be notified to the Committee and a favourable ethical opinion obtained before implementing the amendment. A substantial amendment generally means any significant change to the arrangements for the management of the RTB as described in the application to the Committee and supporting documentation.

7.2 A substantial amendment should be generated by accessing the original application form on the Integrated Research Application System (IRAS).

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 RTB.

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 Request for approval to release tissue to researchers (if not sought as part of the initial application), or changes to the terms of the approval;

7.3.4 A change to the conditions of generic approval

7.3.5 Appointment of a new tissue bank manager (i.e. the person making the application and responsible for further reporting to the REC);

7.3.6 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 RTBs 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 RTB

10.1 Any plans to close the RTB should be notified to the Committee and the HTA 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 RTB.

10.2 Where tissue is transferred to another RTB, the ethical approval for the RTB is not transferable. Where the second RTB is ethically approved, it should notify the responsible Research Ethics Committee by submitting an amendment. 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 opinion l and may, exceptionally, suspend or terminate the approval.