***FRM043: Royal Papworth Hospital Research Tissue Bank Application Form***

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| **Project Title:** |  |
| **Brief Project Description and detailed study protocol** |  |
| **Names of Investigators:** |  |
| **Name of any Project Collaborators outside the Recipient centre:** |  |
| **Is this project supported by the Cambridge BRC?** |  |

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| List of Material required, together with quantity and any special processing requirements.A charge will be made to cover study set up, staff processing and administration costs. This will be agreed with recipients prior to provision of any tissue samples. Project related costs will be reviewed at the time of renewal of a project and/or its transfer agreement. *Please note costs of the Tissue Bank are reviewed each year and will automatically increase in line with inflation; should additional costs be required these will be agreed with the recipient prior to further provision of tissue samples.**It is customary for recipients to provide sample containers with storage solutions and to make transport arrangements.**Once a project has been formally signed off, specimen collection will commence once suitable samples are available. If for any reason researchers are unable to receive these samples they must inform Tissue Bank in advance, otherwise they will be charged regardless of whether or not the samples are accepted.*  * *Tissue Bank will make every reasonable effort to collect samples in line with the agreed terms of the project application. If for any reason Tissue Bank is unable to do this, amendments can be* *made to the project application (after discussion with the Recipient) before further collection takes place, or if agreed the project will be terminated.* * *All theatre specimens are routinely put into Hartmann’s solution and placed into the fridge before sampling. Hartmann’s solution (a mixture of sodium chloride, sodium lactate, potassium chloride and calcium chloride in water) helps keep the cells alive and delays sample deterioration.* |

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| Detailed description of material required | Minimum Quantity (number of samples and size of samples) | *Please supply detailed processing and storage information for each tissue type (a sample processing protocol may be supplied as a separate document if necessary).* |
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| Please give details of any data required to accompany the tissue samples.  *Please note the tissue bank can provide a defined data set in accordance with its ethics approval and a separate R&D project may be required for extensive data collection.* |  |
| Please give the contact details of the person who will arrange to collect the samples on behalf of the Recipient, the mode of transport and destination address. |  |
| Will samples be transferred to a **Project Collaborator outside of the Recipient?** If Yes, please give details. |  |

Research Governance checks:

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| **Please complete the following table by ticking the appropriate Yes or No box** | **Yes** | **No** |
| Will any material leave Papworth hospital site?  *If Yes, a material transfer agreement (MTA) will be required (a template can be provided).* |  |  |
| Is the material to be supplied to another licensed or ethically approved research tissue bank (includes those within commercial organisations)?  *If ‘Yes’ please supply licence number or REC approval letter and all approved documents* |  |  |
| Does the research already have project specific Research Ethics Committee approval?  *If ‘Yes’ please provide a copy of the REC approval letter and all approved documents*.. |  |  |
| Will the research project extract DNA/RNA from the material?  *If ‘Yes’ please see section below regarding reporting of incidental findings following genome sequencing.* |  |  |

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| **Do you wish to obtain the tissue under the Research Tissue Bank Generic REC approval? *If ‘Yes’ please complete the questions below.*** |  |  |
| Has the research been peer reviewed and approved as part of a grant application?  *If ‘Yes’ please provide proof of grant award.* |  |  |
| Is the project Papworth funded research that has been reviewed and supported by the Research and Development Directorate? |  |  |
| Is the research an industrial collaboration that has been reviewed and supported by the Research and Development Directorate? |  |  |
| Is the tissue for student research that is supported by an academic and clinical supervisor? |  |  |
| Will collection of tissue for research require an additional patient intervention? |  |  |
| Will tissue be donated by healthy volunteers? |  |  |
| Will the research produce data that will be clinically relevant to the individuals donating samples? *The terms of PHRTB’s ethics approval does not allow data produced from research using tissue supplied to be used to inform clinical care*. |  |  |
| Will the tissue supplied by PHRTB be used in research involve animal models? |  |  |
| Will the research involve termination of pregnancy or reproductive cloning? |  |  |
| Will the research require tissue from under 16 year olds or from adults without the capacity to consent? |  |  |

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| **Incidental findings following genome sequencing** |  |
| *For the purpose of a Tissue Bank project, an incidental finding is one that has potential health importance, discovered unexpectedly.*  There is no legal obligation to inform of a potential incidental finding, but the lack of a clear legal position does not affect the ethical considerations which should be considered by those undertaking research that could produce incidental findings.  Researchers should consider whether their analysis will lead to the identification of incidental findings, the nature of the test (for example the predictive value of the test) and the chance of false positives. Researchers should consider how any analytical verification will be achieved. |  |
| **Reporting of an incidental finding**  In the event of a researcher wishing to report an incidental finding they are not required to understand the potential severity of the finding, but they will be required to confirm the certainty of the result**.**  The researcher should contact Tissue Bank using [papworth.tissuebank@nhs.net](mailto:papworth.tissuebank@nhs.net). Tissue Bank will require the following information: Tissue Bank ID of the sample analysed; the sequencing protocol used to produce the finding; the result and the likelihood of a false positive. |  |
| **Please read and confirm the following:** |  |
| I have read and understood the statements regarding reporting of incidental findings following genome sequencing |  |

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| **List of Supporting Documents Reviewed** | | |
| *Document* | *Version* | *Date* |
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| **Outcome of review by Tissue Bank Operational Group (TBOG)** |
| **Meeting date:** ***to be entered at Papworth*** |
| **Meeting outcome and project costs: *to be entered by Papworth post TBOG meeting*** |
| **Costs for project under BRC funding criteria: *to be entered by Papworth once eligibility confirmed*** |

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| **Total number of samples to be supplied:** |  | **Proposed end date, or date of review** |  |

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| **Papworth Hospital Research Tissue Bank receives limited core funding to support investigators contributing to the BRC Cardiovascular and Respiratory research themes. Therefore, Tissue Bank can charge reduced fees (which are calculated on a cost recovery basis) when it supports these projects. Once confirmation is received that a project meets this criterion the fees will be adjusted accordingly**.  **I confirm that the project is part of the Biomedical Research Centre’s Cardiovascular & Respiratory research themes and is therefore eligible for Tissue Bank BRC support.** | | | |
| **Authorised by applicant:** |  | **Date** |  |

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| **I agree that this application fully describes the proposed project and I agree to the conditions of approval as described above.** | | | |
| **Signed by applicant:** | ***Form will be returned to applicant for signature after TBOG meeting*** | **Date** |  |

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| **Approved by TBOG:** |  | **Date** |  |