

## **Cost Recovery of Organs & Tissue for Non-clinical use**

### **1. Status – For information**

### **2. Executive Summary**

As a result of the feedback received during the stakeholder engagement event on 3<sup>rd</sup> March 2021 and to reduce any reputational risk for NHSBT whilst ensuring that the requirements of the OTDT strategy are met with regards to supporting Innovation and Research, a revised proposal for the cost recovery model for non-clinical organs was developed, this option removes the perfusion and packaging charges and introduces a set of administration fees for both the initial application for studies accessing non-clinical organs and/or tissues and an annual renewal for the studies accessing non-clinical organs.(see appendix 1).

This revised cost recovery option was presented to and approved by OTDT SMT in March 2021.

The implementation of application fees for studies accessing non-clinical organs and/or tissues will go-live for all new studies approved after 1<sup>st</sup> April 2022. Existing studies will not be affected. These fees will partially recover the administration costs incurred by NHSBT to set up the studies for them to access non-clinical organs and/or tissue and are in line with study set up fees across the research sector. The fees do not recover administration costs incurred by NHSBT in entirety.

### **3. Background**

Actions completed since the previous RINTAG discussions in 2020.

A stakeholder engagement event took place on Wednesday 3<sup>rd</sup> March 2021. This event included a mixture of independent and collaborative researchers and lay members (see appendix 2) to discuss the proposed cost recovery tariffs and the impact of this on researchers accessing un-transplantable organs and/or tissues.

The stakeholder event highlighted significant concerns regarding the implementation of the original model for cost recovery as this is included charges related to packaging and perfusion of non-clinical organs.

The stakeholders were receptive to a fee being applied for the application process in line with study set up fees that are in place across the research sector (circa £1.5-2K per study). There was also a suggestion to also include a smaller annual renewal fee for studies that remain active and continue to accept non-clinical tissues/organs.

Following the stakeholder event, a revised cost recovery model was developed to remove the perfusion and packaging charges for non-clinical organs, to increase the application fee and introduce an annual renewal fee (Appendix 1). This proposed new model for cost recovery of non-clinical organs and tissues was presented to and approved by OTDT SMT in March 2021.

The workstream for the development of a cost recovery process across OTDT has also been adopted under the umbrella of the OTDT Integration Programme now known as OTDT Together. This programme is looking at aligning the directorate by realising OTDT's combined potential to save and improve more lives.

As part of the OTDT Together Programme, the cost recovery group which includes colleagues from the ODT Research Team and Tissue and Eye Services (TES) Research Tissue Bank (RTB), are also developing of an on-line application form to have one point of entry for all applications wanting to access non-clinical organs and/or tissues. This on-line application will replace the paper-based application forms currently in use by the ODT Research Team and the TES RTB and will enable the centralisation of study databases across the directorate. It is envisaged that this on-line application tool will be available for all studies applying to NHSBT after 1<sup>st</sup> April 2022. Further information regarding this will be circulated in early 2022.

## **5. Next Steps**

The timeline for implementation of the revised proposal (i.e. introduction of an application fee for organs and tissue for non-clinical use) remains as April 2022. Therefore, any new studies that are approved by RINTAG or the TES RTB following 1<sup>st</sup> April 2022 will be expected to pay the applicable application/renewal fee prior to the study being able to access non-clinical tissues and/or organs. Information regarding these fees will be provided to applicants at the outset of requests/discussions to ensure that these fees are able to be incorporated into grant applications where necessary.

NHSBT Finance department will create a separate budget line for the income from non-clinical organs to assist with transparency of income. The income from the non-clinical tissues will remain within the existing budget.

Once implemented the ODT Research Project Manager and TES RTB Manager will provide details to NHSBT finance of studies approved by RINTAG to generate invoices for the application/renewal fees. These invoices for initial application fees will be issued alongside a revised Material Transfer Agreement (MTA) to the studies' Principal Investigator (PI). It is expected that access to non-clinical organs/tissue will not be granted until the MTA is signed and returned to NHSBT and the application fee invoice has been paid.

A communication will be sent to all stakeholders early in 2022 to ensure that they are aware of the changes and a FAQ document will be drafted and circulated.

Appendix 1.

**Revised 'cost recovery' model developed following stakeholder feedback.**

<b>Cost Recovery - Application Fee(s)* + Provision of Tissues.</b>	
<p><b>Nominal Pricing Tiers:</b></p> <ol style="list-style-type: none"><li>1. Requests for Organs: <b>£1500 per application</b></li><li>2. Annual Renewal Fee (Organs): <b>£300 per study</b></li><li>3. Standard Requests for Tissues: <b>£90 per application</b></li><li>4. Repeat Standard Request <b>£30 per application</b></li><li>5. Bespoke Request <b>£1500 per application</b></li></ol> <p>*prices may increase in future</p>	<p>Partially recovers the costs of study set up and is in line with fees across the research sector.</p> <p>Partially recovers the costs of maintaining the access to non-clinical organs and providing KPIs to RINTAG.</p> <p>Introduction of an Application Fee(s) for non-clinical tissue requests. Dependent on complexity of the application.</p> <p><b>Provision of Tissues:</b></p> <p>No change. Cost recovery is already being implemented at 10% of clinical cost for academic studies and 20% of clinical cost for commercial studies.</p>

Appendix 2.

Stakeholder event attendees:

Clare Denison – Innovation and Research Lead Specialist (ODT), NHSBT  
Prof Paul Rooney – Head of R&D Tissue and Eye Services (TES), NHSBT  
Agatha Joseph – TES Research Tissue Bank Manager, NHSBT  
Hannah Tolley – Research Project Manager ODT, NHSBT  
Prof Andrew Fisher – NIHR BTRU  
Anais Portet – Research Assistant, Clatworthy Group University of Cambridge  
Michael Wormstone - Professor of Ophthalmology, University of East Anglia  
Dr Nathan Griffiths – Donate for Research Initiative  
Hazel Bentall – RINTAG Lay Member  
Dr John Ferdinand – Senior Research Associate, University of Cambridge  
Rutger Ploeg – Director of QUOD  
Elizabeth Murphy – RINTAG Lay Member  
Dr Krishnaa Mahbubani – Senior Study Manager, University of Cambridge  
Mr John Casey – Chair, Pancreas Advisory Group  
Dr Dan Harvey – National Innovation & Research Clinical Lead

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