Research in ODT: Part recovery for the resources required to support applications through RINTAG

1. Status – Public

2. Executive Summary

NHS Blood and Transplant is committed to working with stakeholders to support innovation and research whenever possible and appropriate. Under RINTAG’s leadership and advice from stakeholders, the process for assessing research study applications has significantly improved and the number of organs and tissues available for research has increased.

Supporting innovation and research involves substantial NHSBT resource and currently these costs are not recovered within ODT.

At ODT SMT, May 2018 it was proposed that a partial cost recovery scheme was introduced, where prospective researchers are charged to cover the cost in part for the resources required to process a research application and any subsequent training/awareness raising related to their study.

SMT agreed the recommendation that there should be a nominal recognition of the cost of the resources required to process a research application, cost per study £300.

3. Action Requested

Note the decision by ODT, SMT that there should be a nominal recognition of the cost of the resources required to process a research application, cost per study £300.

4. Background

Research activity

There are currently 42 active generic studies requiring ‘Relevant materials’ for research purposes, including 3 tissue banks. In addition, there is:

- 1 active specific study requiring access to organ donors
• 9 active specific studies requiring ‘Relevant material’ for research purposes
• 2 Quantitative/ Qualitative studies analysing data/ undertaking interviews

1 ‘Relevant material’ from deceased donors refers to the definition set out by the HTA and encompasses solid organs, associated tissues and/or biopsy samples.

INOAR

A RINTAG Sub-Group - Increasing the Number of Organs Available for Research (INOAR) - was established in 2017 to make recommendations on what more could be done to address the gap between the availability of and demand for organs for research purposes. INOAR made recommendations to RINTAG and SMT 2017 and work is underway to implement the recommendations from the subgroup commencing with the removal of heart, lungs and the diabetic pancreas for research. The introduction of INOAR could potentially result in an additional 184 Lungs, 87 Hearts and 42 diabetic pancreas being available for research per year based on 2017 QUOD hospital data.

Current Resource Allocation

The resources for supporting research applications to the Organ Donation and Transplantation directorate has been significantly increased in recent years, with the establishment of a new ODT research team. This has helped to ensure that studies are provided with the support and advice necessary to take forward new research proposals and that the necessary approvals are in place for any studies that receive ODT support. The team also undertakes changes to NHSBT operations to ensure that studies run smoothly with minimal impact to the operational teams. This includes training for SNODs and CLODs and gaining support from other stakeholders, such as NORS teams and ICU teams. Without this co-ordinated approach, some of the more complex research programmes currently underway might not have been able to proceed.

The costs for ODT support for each research applications:

<table>
<thead>
<tr>
<th>NHSBT approval process</th>
<th>Cost</th>
</tr>
</thead>
<tbody>
<tr>
<td>Generic study</td>
<td>£565</td>
</tr>
<tr>
<td>Specific study</td>
<td>£7,858</td>
</tr>
</tbody>
</table>

A breakdown of these costs are provided at Annex A.

The perfusion and packaging costs for organs retrieved via a specific route range from £69.48 – £1,981.00

Guidelines

MPD 565, Guidelines for the use of Donated and Patient Material state:
Donation material supplied to an external organisation must be paid for on a full cost recovery basis. Costs for supplying external requests should be part of any research grant application.

No charge will be made for internal NHSBT research/studies which are funded by NHSBT. To date, ODT has not undertaken any cost recovery.

5. Proposal

Prospective researchers submitting a formal application via RINTAG are required to pay £300 per application in recognition of the cost of the resources required to process a research application.

No charge will be made for internal NHSBT research/studies which are funded by NHSBT.

No charge will be made for the removal of organs for research.

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Appendix A.

| Direct pathway, generic study | 12 hours | 9.5 hours | £565 |
| Complex pathway, | 83.5 hours | 203.5 hours | £7,858 |
Appendix B.

Perfusion and Packaging costs per organ (specific study)

<table>
<thead>
<tr>
<th>Abdominal</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Kidney</td>
<td>£69.48</td>
</tr>
<tr>
<td>Liver</td>
<td>£1128</td>
</tr>
<tr>
<td>Pancreas</td>
<td>£958.80</td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Thoracic</th>
<th></th>
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</thead>
<tbody>
<tr>
<td>Heart</td>
<td>£1,744</td>
</tr>
<tr>
<td>Lung</td>
<td>£1,981</td>
</tr>
</tbody>
</table>

*Perfusion (including drugs) and packing costs