

**NHS BLOOD AND TRANSPLANT  
ORGAN DONATION AND TRANSPLANTATION DIRECTORATE  
RESEARCH, INNOVATION AND NOVEL TECHNOLOGIES ADVISORY GROUP MEETING  
Tuesday 25 May 2021, from 10:30 – 14:30, via Microsoft Teams**

**MINUTES**

**Present**

Gavin Pettigrew	GP	Chair, RINTAG
Liz Armstrong	LA	Head of Transplant Development
Richard Baker	RB	Joint Clinical Governance Lead
Marius Berman	MB	Associate National Clinical Lead, Organ Retrieval
Sarah Cross	SC	QUOD Representative
Alison Deary	AD	Head of Clinical Operations, NHSBT
Aileen Feeney	AFe	RINTAG Lay Member
Andrew Fisher	Afi	NIHR BTRU Representative
Claire Foley	CF	Observer
John Forsythe	JF	Medical Director, OTDT, NHSBT
Victoria Gauden	VG	National Quality Manager, NHSBT
Dan Harvey	DH	National Innovation & Research Clinical Lead, OTDT
Agatha Joseph	AJ	Laboratory Scientist, NHSBT
Emma Lawson	EL	Research & Innovation Manager, NHSBT
Lorna Marson	LMa	UKODTRN
Lisa Mumford	LMu	Head of OTDT Studies, NHSBT
Elizabeth Murphy	EM	RINTAG Lay Member
Rutger Ploeg	RP	Director of QUOD
Karen Quinn	KQ	Assistant Director, Service & Commissioning Development, NHSBT
Paul Rooney	PR	Research & Development Manager, NHSBT
John Stirling	JS	Attending on behalf of John Richardson
Doug Thorburn	DT	Chair, Liver Advisory Group
Hannah Tolley	HT	Research Project Manager, NHSBT
Rajamiyer Venkateswaran	RV	Chair, CTAG Hearts Advisory Group
Chris Watson	CW	Chair, Kidney Advisory Group
Steve White	SW	Chair, Pancreas Advisory Group

**Apologies**

Oluwayomi Adegaju  
 Kyle Bennett  
 Akila Chandrasekar  
 Jasvir Parmar  
 Rommel Ravanan  
 John Richardson  
 Maggie Stevens  
 Michael Stokes

**In attendance**

Heather Crocombe (Minutes) HC Clinical & Support Services, NHSBT

No.	Agenda Item	Action
1.	<b>Welcome and Apologies</b> GP welcomed everyone to today's meeting. Apologies were received as shown above.	



	<p><b>Action: To take this issue to the Islet Consortium and Islet Steering Group, and report back.</b></p> <p><b>Action: To add this item to the Agenda for the next RINTAG Meeting, for discussion.</b></p> <p><u>Update</u> To remain on the Agenda for the next RINTAG Meeting.</p>	JC  SW  HC
<b>AP13.2</b>	<p><u>Shipment of Organox between Centres</u> The process of shipment of Organox between Centres has previously been agreed at LAG however, given the time that has passed, and the issues caused by COVID, it may be worth putting this before LAG again.</p> <p><b>Action: To raise the issue of Organox shipments between Centres again with LAG, and report back.</b></p> <p><u>Update</u> CW advised that a situation arises when a liver is (i) already on the machine and (ii) the recipient centre decides they don't want it so are going to give it to another centre. CW will contact centres to garner further information regarding how often this situation arises, action taken etc. and take the Protocol to the next LAG meeting for approval.</p> <p><b>Action: To raise the issue of Organox shipments between Centres again with LAG, and report back.</b></p>	CW       CW
<b>Point 5</b>	<p><u>Study Re-Ranking</u> <b>Action: To amend the wording for the Edinburgh Study ranked 56, to show that this is an MRC funded study, so it is reviewed.</b></p> <p><u>Update</u> Action completed.</p>	HT
<b>Point 7.2</b>	<p><u>Updates to the Research Organ Allocation Policy (POL263) for INOAR</u> Definitions previously agreed at RINTAG went to ODT Care and then NHSBT Care for final sign-off. There may be the opportunity in the future to revisit definitions, however not at the current time as NHSBT Care has reviewed and agreed definitions and consistency has been applied with other directorates. When the paper was initially discussed at RINTAG in ****, no objections were raised by the membership</p>	
<b>Point 15</b>	<p><u>Cost Recovery of Organs/Tissues used in Research</u> CD and PR presented various options to resolve this issue to the wider Business Developments Team (BDT), and the BDT have opted for a tiered approach <b>Action: To volunteer to work with CD on the implementation of the tiered approach solution which has been agreed by BDT.</b></p> <p><u>Update</u> This piece of work has been parked for the moment, pending project management resource. <b>To be added to the Agenda for the next RINTAG Meeting</b></p> <p><u>Points made</u></p> <ul style="list-style-type: none"> <li>• Tissue Services has already implemented a costs recovery system for non-clinical tissues, which works well</li> <li>• QUOD has costs recovery in place, and will pass a copy of the agreed protocol to GP for information</li> </ul>	LA/CD/PF/AF/ HB/JC/DH/VG RP/RB   HC
<b>4.</b>	<b>Research Activity</b>	
<b>4.1</b>	<b>Consent</b> <b>Research Consent/Authorisation Rates RINTAG(21)1</b>	


	<p>This paper summarises how generic research consent/authorisation rates changed over the last ten years in the UK. Research consent/authorisation rates were analysed for actual organ donors (where at least one organ was removed for the purposes of transplantation) from 1 January 2011 to 31 December 2020.</p> <p><u>Conclusion</u></p> <p>The overall UK consent/authorisation rate for research was 83% in 2011 and has risen to 92% in 2020. There is slight variation by nation.</p> <p><u>Points made</u></p> <ul style="list-style-type: none"> <li>• Donor families are still very receptive to supporting research projects, even in emotional trying situations</li> </ul>	
4.2	<p><b>Availability of Organs for Research RINTAG(21)2</b></p> <p>This paper investigates the pathway of organs which have been retrieved and not transplanted, to assess the availability of organs for research. It also identifies the number of such organs which were offered to and received by research studies between 1 January 2020 and 31 December 2020. Research outcome was split into three categories: (i) no generic research consent (ii) used for research (under generic or specific consent) and (iii) organ disposed of with generic research consent</p> <p><u>Conclusion</u></p> <ul style="list-style-type: none"> <li>• The total number of organs retrieved and not transplanted has steadily increased over time</li> <li>• The proportion of these organs which have consent/authorisation for research has increased to 95% in 2019</li> <li>• The impact of the Coronavirus pandemic has meant that the number of organs retrieved and not transplanted in 2020 has been lower than usual</li> <li>• 299 organs have been used for research in 2020</li> <li>• The proportion of discarded organs where generic research consent/authorisation was given was 13% in 2015, compared to 47% for the period January – December 2020</li> <li>• During January – December 2020, 505 retrieved but untransplanted organs were offered to researchers through the National Allocation Scheme. 262 of the 505 organs offered were accepted by studies on the ODT Research Registry. In addition to this 262, an additional 37 organs were used, but not offered through the NAS</li> <li>• Utilised research organs were distributed across many studies, which suggests that studies which were ranked lower through the allocation scheme were still able to receive organs</li> </ul> <p><u>Points made</u></p> <ul style="list-style-type: none"> <li>• Main reasons for organs not being accepted by studies appear to be the timing of the offer (ie. during unsocial hours) and cold ischaemia duration</li> <li>• It is hard to rely on 2020 data, as it was such an unusual year</li> <li>• For heart and lungs, when no cardiothoracic retrieval team is available, only the heart can be retrieved if the abdominal team can take it. Is it acceptable then in that situation for a certified NORS lung surgeon or cardiothoracic person from the research team to attend to retrieve the lungs?</li> <li>• Where offers are made during unsocial hours, do we ask researchers ahead of time to cover that, and if they are unable to, to reduce their expectations as to the organs and tissue that will be offered</li> <li>• Are we going to offer organs for research after we have spent all the money moving towards transplantation, or are we retrieving for research only? Costs recovery should be built into any changes from the outset.</li> </ul> <p>Optimisation of cardiothoracic organs will be addressed further down the agenda</p>	

5.	<p><b>Study Re-Ranking and Survey Feedback RINTAG(21)3 and 3(a)</b>  <b>Survey Feedback RINTAG(21)3</b></p> <p>One of RINTAG's first objectives when it was set up in 2017 was to design a ranking and allocation system for studies to receive organs for research. Before this, organs were allocated on a geographical basis. The system designed by RINTAG considers several factors to calculate a score:</p> <ul style="list-style-type: none"> <li>• Whether a study can transplant the organ it receives</li> <li>• Whether the study can be peer-reviewed</li> <li>• How many organs the study requires (feasibility)</li> <li>• Whether the study is basic science, clinical or is unrelated to transplant</li> </ul> <p>The following secondary categories are used as tiebreakers:</p> <ul style="list-style-type: none"> <li>• Collaboration with other institutions</li> <li>• Use of novel technology</li> <li>• Alignment to ODT Strategy</li> </ul> <p>A survey was circulated to all active researchers in early 2021, and 13 people responded (which equates to approximately half of all current open studies, which is disappointing). They agreed that whilst the current system is undoubtedly an improvement on the previous one, they identified issues and provided feedback on the system:</p> <p><u>See survey results for full details, but key points:</u></p> <ul style="list-style-type: none"> <li>• Little movement up/down the ranks. If a study has wide acceptance criteria and is placed near the top, it prevents studies lower down the ranking from receiving much tissue, if at all</li> <li>• Rare organ types. Studies that wish to receive rare organs are often separated by very small margins (often a single point), but this results in the top ranked study receiving all of the tissue and others not receiving any</li> <li>• The most disagreement was around whether research that is not directly related to ODT should be lower ranked. One suggestion was that members of the public, donor families and transplant recipients could be consulted and asked to help define research priorities</li> </ul> <p>Other suggestions included incorporating:</p> <ul style="list-style-type: none"> <li>• Upcoming grant deadlines</li> <li>• Geography</li> <li>• Specific organ requirements (eg. fatty livers)</li> <li>• Whether the project can improve (in the long term) the quality of life of potential recipients</li> <li>• Study progress (in terms of meeting their Protocol)</li> </ul> <p>Suggestions for increasing acceptance overall were:</p> <ul style="list-style-type: none"> <li>• Helping with transport costs</li> <li>• Mandating that the NORS Team will take organs for research if there is appropriate consent/authorisation</li> <li>• Earlier notice in order to minimise the cold ischaemic time</li> <li>• Putting details of machine perfusion status in the offer message</li> </ul> <p>Most of the respondents were positive or neutral about the understandability and fairness of the current system. Respondents were negative about the visibility of the system.</p>	
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	<p>After discussion, it was agreed that we should look into how we can refine/tweak the prioritisation and ranking system, and how best to allocate organs for research. (Having a study which is always “number 1” is unhelpful). It is essential that we get widespread input into this and ensure that we hear all voices.</p> <p><b>Study Re-Ranking RINTAG(21)3(a)</b> HT shared the re-ranking spreadsheet with attendees and asked for any comments or concerns.</p> <ul style="list-style-type: none"> <li>The question was raised as to whether there are enough organs every year to provide the numbers requested by researchers. HT advised that pre-COVID, for most organ types we did have enough organs to meet the requests. Since COVID, studies have been aware they would receive less than requested.</li> </ul>	
6.	<p><b>New Studies and Resubmissions RINTAG(21)4(a) to 4(l)</b></p> <p><u>Study 113 – Evaluation of the Organ Donation (Deemed Consent) Act 2019 in England – London School of Hygiene &amp; Tropical Medicine (LSHTM)</u> See paper for full details, but key points:</p> <ul style="list-style-type: none"> <li>The aim is to evaluate the effects of the changes in the organ donation system associated with the Organ Donation (Deemed Consent) Act 2019, with reference to deceased donor consent rates and to explain any changes observed by investigating:</li> <li>the behaviour and experiences of staff;</li> <li>the behaviour and experiences of relatives and nominated representatives of potential and actual deceased donors; and</li> <li>the influence of changes in the healthcare system, including those associated with the COVID-19 response and the NHS’s recovery post-COVID</li> </ul> <p>Current Status of the Study: Applying for HRA and REC approvals. Awaiting guidance from NHSBT Information Governance regarding the suitability of taking consent from the donor family at the time of donation.</p> <p><b>Decision made: There were no objections raised to this Study</b></p> <p><u>Study 119 – Role of Stem Cell Derived Extracellular Vesicles in Reducing Ischaemia-Reperfusion Injury in Human Donor Hearts – Newcastle University</u> See paper for full details, but key points:</p> <ul style="list-style-type: none"> <li>The aim is to study the impact of a type of stem cell (human amniotic epithelial cells (derived from the placenta)) on human hearts during warm, oxygenated warm blood reperfusion, and estimate the reduction in ischaemic reperfusion injury</li> <li>The request is for 15 untransplantable hearts from DBD donors through INOAR. A CT NORS Team must be attending so that that heart can be perfused with cardioplegia.</li> <li>Current Status: Study aiming to start in October 2021</li> <li>Provisional ranking: No. 3 out of 5 heart studies</li> </ul> <p><b>Decision made: There were no objections raised to this Study</b></p> <p><u>Study 120 – A Preliminary Study to assess Cadaveric Rectus Sheath Fascia as a Potential Bioresource – Mr James Richards, Mr Andrew Butler, Prof. Paul Rooney</u> See paper for full details, but key points:</p> <ul style="list-style-type: none"> <li>The aim of this study is to characterise and assess the strength of newly retrieved donor rectus sheath fascia, to optimise a decellularization and cryopreservation protocol for donor rectus sheath fascia, to characterise</li> </ul>	

	<p>and assess the strength of decellularized and cryopreserved donor rectus sheath fascia, to assess the effect of cryopreservation and decellularization on the integrity and structure of donor rectus sheath fascia, and to assess repopulation <i>in vitro</i> of decellularized donor rectus sheath fascia by mesenchymal stromal cells.</p> <ul style="list-style-type: none"> <li>• This study requests 20 retrievals of rectus sheath fascia from organ donors in the Eastern region. The retrievals must take place at hospitals covered by NHSBT's HTA Licence (Addenbrooke's and Queens, Romford). The Eastern team of Specialist Nurses already take consent from donor families for rectus sheath fascia for clinical purposes.</li> <li>• Current status: Still in operational work-up, not yet ready to start.</li> </ul> <p><b>Decision made: There were no objections raised to this Study</b></p> <p><u>Study 121 – Development of Hybrid 3D Scaffolds for Kidney Tissue Engineering by Combination of Human Decellularized Extracellular Matrix and Polymer – University of Edinburgh</u></p> <p>See paper for full details, but key points:</p> <ul style="list-style-type: none"> <li>• The aim is to investigate the suitability of hybrid scaffolds over kidney cell growth and function. The team would like to build hybrid 3D scaffolds that contain both human kidney and synthetic polymer that can be used for testing on kidney cells. The team has already been using rat kidneys to produce scaffolds and require human kidneys for comparison.</li> <li>• The study requires 5 untransplantable kidneys through the National Allocation Scheme</li> <li>• Current status: REC approval in progress, provisional ranking of 8</li> </ul> <p><b>Decision made: There were no objections raised to this Study.</b></p> <p><u>Study 122 – Quality in Organ Donation QUOD-MRC – Expansion to include Whole Organ Collection and Research of Heart, Lung, Pancreas, Kidney and Liver: Kidney Atlas Project – Nottingham UCL and Oxford</u></p> <p>See paper for full details, but key points:</p> <ul style="list-style-type: none"> <li>• The aim is to assess and condition donor kidneys using integrated imaging, perfusion, and molecular profiling</li> <li>• The request is for 76 untransplantable kidneys by 31 August 2024</li> </ul> <p><b>Decision made: There were no objections raised to this Study.</b></p> <p><u>The PLUS Study</u></p> <ul style="list-style-type: none"> <li>• The PLUS Study Protocol was provided to attendees for information, however, this study has not yet been signed off by the Sponsor.</li> </ul> <p><u>Points made</u></p> <ul style="list-style-type: none"> <li>• The point was raised that some of the studies which have been resubmitted have drastically increased the number of organs they are asking for. The idea of submitting studies to RINTAG for approval is that a study is a discrete piece of work with a definite number of organs required. Agreed that HT will feed back to these studies for further information.</li> </ul> <p><b>Action: HT to go back to researchers for justification for large increases in organs required.</b></p>	HT
7.	Innovation	
7.1	DCD Heart Activity <a href="#">RINTAG(21)5</a>	



	<p>This report contains information on DCD heart retrieval and transplant activity from 1 February 2020 – 31 December 2020</p> <p>See paper for full details, but key points:</p> <ul style="list-style-type: none"> <li>• Outstanding DCD heart supplementary forms and DCD heart passport forms for the period 1 April 2020 – 31 December 2020, as of 8 March 2021: 4</li> <li>• See <i>Figure 1</i> for DCD heart retrieval activity by quarter and retrieval team</li> <li>• See <i>Figure 2</i> for DCD heart retrieval activity by quarter and transplant centre</li> <li>• See <i>Table 2</i> for DCD heart retrieval activity by period and centre</li> <li>• See <i>Table 3</i> for DCD heart patient outcomes at 30 days post-transplant, by centre</li> <li>• See <i>Table 4</i> for DCD heart offers recorded on the UKTR as being made to participating centres and results, by financial year</li> </ul>	
7.2	<p><b>NRP RINTAG(21)6</b></p> <p>This report presented information on NRP activity in the UK for the period 1 April 2015 – 31 March 2021 and compares to standard DCD retrievals over the same period. Note that NRP is recorded against the team who performed NRP, which may be different from the main retrieval team in attendance. See paper for data:</p> <p> RINTAG(21)6 - NRP quarterly report - Mar</p> <p><u>Points made</u></p> <ul style="list-style-type: none"> <li>• There are two centres currently doing abdominal NRP in the UK (Newcastle and Cambridge)</li> <li>• A very strong Business Case for abdominal NRP was produced, we have agreed a National Protocol, we have sorted out requirements for new centres, we have suggested training regimes and mentoring, and have Information Governance in place</li> <li>• The Royal Free and Cardiff are starting at the moment, and the only centre which hasn't expressed an interest is Manchester</li> <li>• We have demonstrated the clinical benefit and financial/fiscal benefit for NRP. The Business Case prepared readily demonstrated both of those things. NHSBT has found funding in its budget for NRP for the last few years. The problem arises because this funding is now to be in perpetuity</li> <li>• The point was made that NRP is discussed in several other forums as well, so is it essential to keep it within the RINTAG forum? After discussion, it was agreed that <u>TA-NRP</u> should remain on the RINTAG agenda.</li> </ul>	
7.3	<p><b>Uncontrolled DCD Project – Cambridge RINTAG(21)7</b></p> <p>Dominic Summers presented details of this Project to attendees.</p> <p>Key points:</p> <ul style="list-style-type: none"> <li>• Uncontrolled DCD refers to organ retrieval after a cardiac arrest that is unexpected and from which the patient cannot or should not be resuscitated</li> <li>• DS spent some months in Santander in Spain (with funding from ESOT) looking at Spain's Uncontrolled DCD Project (UDCD)</li> <li>• The UDCD programme provides large numbers of high-quality kidneys for transplantation in Spain</li> <li>• Not having a UDCD programme in the UK denies the opportunity for donation for many families. Combined with novel technology, UDCD has the potential to greatly increase the number of kidneys available for transplantation in the UK</li> </ul>	



	<ul style="list-style-type: none"> <li>• The researchers on this study are currently in the process of applying for grants (primarily from the NIHR)</li> <li>• DS has already engaged with coroners, and they are keen to be involved</li> </ul> <p>The Study will be across four Workstreams:          WS1. Delivery of donation pathway          WS2. Family Experience: Qualitative assessment          WS3. Resuscitation: Quantitative assessment of resuscitation          WS4. Organ Assessment: Feasibility of collecting biopsies, rapid analysis and use of ex-vivo perfusion</p> <p><u>Questions raised</u>  <i>Qu: How will the researchers protect themselves from complaints and press involvement?</i> The Study panel is trying to ensure that the programme is as strong as possible, however there is the potential for families to be unhappy with this process.</p> <p>JF advised that some time ago, Edinburgh had tried to do this following a working visit to Madrid. Issues could arise with the practicality of getting a quick decision from coroners' officers, with local press, and having access to staffed theatres.</p> <p><b><i>Decision made: There were no objections raised to this Study at this early stage and a full application should come back to RINTAG for approval when more of the details are finalised. After the meeting DS was also advised to contact the HTA for advice.</i></b></p>	
	~ Lunch ~	
8.	<p><b>INOAR RINTAG(21)8</b></p> <p>EL introduced herself to attendees, advising that she has taken up the post of OTDT Research Manager. EL advised that one of her first tasks in her new role was to carry out a 3-month review of INOAR and present the findings to today's meeting</p> <p><u>See paper for full details, but key points:</u></p> <ul style="list-style-type: none"> <li>• In 2017, NHSBT's Research, Innovation and Novel Technologies Advisory Group (RINTAG) formed a sub-group to increase the number of organs available for research. This sub-group was named INOAR</li> <li>• Owing to a number of software/electronic and operational challenges and the COVID pandemic, the initial go-live date of November 2018 was unfortunately not achieved (went live 13 January 2021)</li> <li>• All SNODs are now in a position to approach donor families to consent or provide authorisation for the removal and storage of the heart, lungs, and diabetic pancreas for research</li> <li>• The data shown in this paper covers the period 1 February 2021 – 30 April 2021, following an audit of potential donors</li> <li>• 35 hearts were offered through INOAR in this time period, but unfortunately none of these offers resulted in a heart being retrieved for research</li> <li>• There were 24 offers for lungs. 17 of these were accepted leading to 9 removals</li> <li>• There have been 7 donors with diabetes in an INOAR-suitable hospital during the data collection period, 6 of the donor families consented for the removal of their relative's pancreas for research. In 2 cases, all centres declined organs for transplantation, therefore the donor did not proceed to</li> </ul>	

	<p>theatre. Of the 4 pancreases offered, all were accepted and removed for research</p> <p>The proposals made:</p> <ul style="list-style-type: none"> <li>• Scope the feasibility of including blood samples for INOAR organs to mirror those that are currently sent with transplantable organs which are subsequently declined and used for research</li> <li>• Open dialogue between researchers and NORS Leads to assess how to improve acceptance of INOAR organs for research (whilst ensuring that teams are not asked to operate outside of their scope of practice and no clinical risk to other organs accepted for transplant)</li> </ul> <p><u>Discussion Points</u></p> <ul style="list-style-type: none"> <li>• Attendees welcomed any methods which would increase the number of organs available for research</li> <li>• Those teams who facilitate retrieval for research more often (which often involves several hours more work) could be recognised and thanked in some way, and a report could be presented at RINTAG</li> <li>• Coroners' restrictions can be put in place prior to retrieval commencing</li> </ul>	
9.	<p><b>QUOD Report RINTAG(21)9</b></p> <p>Sarah Cross presented QUOD data as of 1 March 2021. See paper for full details, but key points:</p> <p>QUOD Bioresource Key Figures:</p> <ul style="list-style-type: none"> <li>• Donors: 5,257</li> <li>• Samples taken: 95,987 in total, including:</li> <li>• 49,665 blood samples</li> <li>• 11,522 urine samples</li> <li>• 13,372 kidney samples (6,773 biopsies)</li> <li>• 7,020 liver samples (3,527 biopsies)</li> <li>• 7,667 ureter samples (3,873 biopsies)</li> <li>• 3,936 spleen samples (3,936 biopsies)</li> <li>• 151 BAL (bronchoalveolar lavage) samples</li> <li>• 2,654 heart samples (1,334 biopsies)</li> </ul> <p>QUOD Samples Issued to Applications:</p> <ul style="list-style-type: none"> <li>• Biobank items issued: 27,217</li> <li>• Research project applications: 62</li> <li>• New applications (at preliminary stage): 14</li> <li>• Applications approved by Steering Committee: 51, 35 completed, 16 in progress</li> </ul> <p><u>Discussion points following presentation</u></p> <ul style="list-style-type: none"> <li>• Will there ever be a situation where QUOD will be unable to meet demand, or the opposite, that there could be too many samples in the Biobank? SC advised that there will always be rare donor type samples that the Biobank will require more of, but in general, demands are met.</li> </ul>	
10.	<p><b>Shipment of SherpaPak hearts between centres</b></p> <ul style="list-style-type: none"> <li>• SherpaPak is a CE mark and FDA approved device – it is essentially an icebox which maintains a donor heart at between 4 and 8 degrees centigrade (average temperature of 4.8). The box contains a sterile canister into which the heart is placed. The temperature is automatically measured every 20 mins and data can be downloaded post-use.</li> </ul>	

	<ul style="list-style-type: none"> <li>Over 800 hearts have been transplanted worldwide using this method since its inception in 2018, and none of those hearts have been refused post transportation</li> <li>SherpaPak purchase is currently charity funded</li> <li>What RJ is looking for from today's RINTAG attendees is approval for use of SherpaPak boxes via NHSBT drivers. The heart requires no monitoring during transit and using these will therefore save a huge amount of money in transportation costs, and the costs of having to have a team travelling with an organ</li> <li>LA asked if a call could be set up between herself, RV and Debbie Macklam, to discuss further details, together with any risks</li> </ul> <p><b>Action: RV to liaise with LA regarding setting this meeting up</b></p>	RV/LA
11.	<p><b>Clinical Governance Update RINTAG(21)10</b> DM was unfortunately unable to present this item at today's meeting.</p>	
12.	<p><b>COVID Antibody project</b> MW was unfortunately unable to present this data at today's meeting.</p>	
13.	<p><b>Update – Donor Optimisation Care Bundle Development</b> GH was unfortunately unable to present this item at today's meeting.</p>	
14.	<p><b>CTU – Update RINTAG(21)11</b> This paper provided an update on the clinical trials in organ donation and transplantation that the NHSBT Clinical Trials Unit is currently managing. Please see paper for full details, but key points:</p> <ul style="list-style-type: none"> <li>There are currently 8 trials in set-up and recruitment. A further trial, ITOPS, is currently in close-down prior to data analysis, and there is one additional study for which we are awaiting confirmation of funding</li> <li>PITHIA, SONAR and PLUTO were paused due to the COVID pandemic</li> <li>SONAR 12M is in recruitment, and we are collecting additional data from the original SONAR study to see if SONAR 2<sup>nd</sup> Phase can commence</li> <li>TWIST is in set-up. This is being run by the Herrick Trust. 130 participants have been recruited thus far</li> <li>PLUS Study. The start of the study was delayed by the COVID pandemic</li> <li>DeFat Study. This is in the protocol and set-up phase at the moment</li> <li>SIGNET. This study is in set-up currently</li> </ul> <p><u>Points made</u></p> <ul style="list-style-type: none"> <li>Co-enrolment. SIGNET is going to involve a very large percentage of UK donor activity. The effect of statin use in SIGNET could conceivably confound interpretation of any further study performed at recipient level. Randomised organs may well find themselves in other transplant studies, so a data sharing arrangement at study level has been added to the Protocol. This will assist in helping SIGNET be aware of what perfusion studies a particular organ might have been exposed to, and other studies would be aware if a donor has been treated with a statin during their period of donor management</li> </ul>	
15.	<p><b>Any Other Business</b> None</p>	
	<b>Date of next meeting: Wednesday 3 November 2021 at 10:30</b>	

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To be ratified