NHS BLOOD AND TRANSPLANT
ORGAN DONATION AND TRANSPLANTATION DIRECTORATE
RESEARCH, INNOVATION AND NOVEL TECHNOLOGIES ADVISORY GROUP MEETING
Tuesday 24 May 2022 from 09:30 – 13:00, via Microsoft Teams

MINUTES

Attendees:

Gavin Pettigrew	GP	Chair, RINTAG
Liz Armstrong	LA	Head of Transplant Development, OTDT
Sarah Cross	SC	QUOD National Operational Coordinator
Andrew Fisher	AF	NIHR BTRU Representative
Victoria Gauden	VG	National Quality Manager, NHSBT
Dan Harvey	DH	National Innovation & Research Clinical Lead, OTDT
Emma Lawson	EL	Research & Innovation Manager, NHSBT
Liz Middlehurst	LMi	Head of Operations, Organ Donation
Lorna Marson	LMa	UKODTRN
Ian Currie	IC	National Clinical Lead for Organ Retrieval
Lisa Mumford	LMu	Head of OTDT Studies, NHSBT
Ulrike Paulus	UP	Consultant Haematologist, Tissues and Cell Donation and Transplantation
Paul Rooney	PR	Head of Research & Development, Tissue and Eye Services
Maggie Stevens	MS	Specialist Nurse for Research, OTDT
Lucy Roberts	LR	Research Project Manager, NHSBT
James Hunter	JH	Clinical Science Coordinator, QUOD
Maria Kaisar	MK	Researcher in Transplant Science
Richard Baker	RB	Joint Clinical Governance Lead
Marius Berman	MB	Associate National Clinical Lead, Organ Retrieval
Debbie Macklam	DM	Senior Commissioning Manager, NHSBT
Doug Thorburn	DT	Chair of Liver Advisory Group, NHSBT
Elizabeth Murphy	EM	Lay Member, RINTAG
Helen Thomas	HT	Head of Clinical Trial Statistics, NHSBT CTU

Henk Giele (Item 4.1)
Colin Wilson (Item 4.2)
Luke Williams (Item 4.3)
Jasvir Parmar (Item 4.4)
Stefanie Curry (Item 4.4)
Jennifer Baxter (Item 4.4)
Kourosj Saeb Parsy (Item 5.1)
Krishnaa Mahbubani (Item 5.1)

Apologies:

Derek Manas	Rommel Ravanan
Akila Chandrasekar	Mick Stokes
Rachel Hilton	Gordon Turpie
Rachel Johnson	Rutger Ploeg
Steve White	Aileen Feeney
John Richardson	Karen Quinn
Kyle Bennett	Michelle Willicombe
Andy Butler	Venkateswaran Rajamiyer

No.	Agenda Item	Action
1.	**Welcome and Apologies** GP welcomed everyone to today's meeting and introduced Lorna Marson as the new MD for NHSBT R&D and Lucy Roberts as the new ODT Research Project Manager. Apologies were received as shown above.	
2.	**Declarations of Interest in relation to the Agenda** There were no declarations of interest in relation to today's Agenda	
3.	**Minutes of the Research, Innovation and Novel Technologies Advisory Group Meeting held on 03 November 2021** **RINTAG(M)(21)2 03 11 21**	
3.1	**Accuracy of the Minutes** The Minutes of the RINTAG meeting which took place on 03 November 2021 were deemed to be a true and accurate reflection of the content of that meeting	
4.	**New Studies for Approval RINTAG(22)1 May 2022** The following studies have gone live since the last RINTAG meeting: • **Study 116 Perfused Liver Utilisation Study (PLUS)- A randomised controlled trial of normothermic machine preservation in extended criteria livers;** run by Oxford University and NHSBT CTU. • **Study 120 A preliminary study to assess cadaveric rectus sheath fascia as a potential bioresource;** run by NHSBT • **Study 121 Development of hybrid 3D scaffolds for kidney tissue engineering by combination of human decellularized extracellular matrix and polymer;** run by the University of Edinburgh • **Study 125 Evaluation of consent processes for interventional donor research in the context of deemed consent;** Sponsored by City, University of London • **Study 128 Optimising Normothermic Perfusion of the Kidney;** run by the University of Oxford Other study updates: • **Study 75 The PITHIA Trial - The Pre-Implantation Trial of Histopathology In renal transplant Allografts-** is now completed • **Study 122 Quality in Organ Donation: QUOD-MRC- Expansion to include Whole-Organ Collection and Research (Kidneys);** run by the University of Oxford, is expected go live in due course • **Study 129 Normothermic machine perfusion of discarded human livers for development of ischaemia reperfusion injury model and testing of related therapeutic interventions;** run by UCL, is expected to go live in due course	
4.1	**Study 134:** Efficacy and mechanism of sentinel skin flap reduction of solid organ (lung) transplant rejection: A randomised controlled trial **RINTAG(22)2 & RINTAG (22)3**	

	RINTAG(22)2 Study 134 app form- Henk (RINTAG(22)3 Study 134 Protocol.pdf Please see paper for full details, but key points: • Chief Investigator – Henk Giele attended to present (henk.giele@nds.ox.ac.uk) • Secondary contacts – Jo Cook (ssftrial@nds.ox.ac.uk) and Claire Brittain (clare.brittain@ndorms.ox.ac.uk) • Estimated study start date: 01.03.2023, Study end date: 01.03.2028 • Managed by Oxford Clinical Trials Research Unit • NIHR funding received • REC & HRA Approvals not yet received • Re-design of previously approved study looking at SSF in lung transplants, as a randomised controlled trial. • 76 patients will get lung & skin, 76 lung only. • GP asked what the plan is for recruitment and schedule. HG confirmed that the plan is to recruit January/February 2023. • Primary end point is lung rejection events. • VG asked for clarification on the NORS teams and whether it would be one team that would take the skin flaps. HG explained that they had previously sent a registrar or trainee to retrieve the skin as part of the NORS team, which means individuals at each centre will need to be identified to go with each NORS team in the hopes that, in the long term, this will become part of NORS team activity. At this stage, extra support will be provided for this purpose. VG conscious that there was previously an incident with removal of skin flaps from a donor. HG explained that this was one of the very first ones done and adequate training wasn't in place, however he hoped to reinstate the component at the NHSBT masterclass where they did skin flap and abdominal wall retrieval. • GP asked whether skin would be retrieved irrespective of randomisation. HG clarified that they would only retrieve the skin if randomised to skin to reduce waste. • It was mentioned that there may be potential use of military trainees for retrieval of skin flaps. There were no objections raised. ***Decision made: Attendees agreed that this study could be granted approval with conditions such as obtaining external approvals.***	
4.2	**Study 79:** OrQA (Organ Quality Assessment) retrospective organ photography audit **RINTAG(22)4** RINTAG(22)4 Study 79 app form- ORQA.p Key points: • Chief Investigator- Colin Wilson attended to present (colin.wilson6@nhs.net) • Proposed start date: 01.11.2022 • Looking at retrospective organ photographs (3200) for quality assessment. CW asking for these to be released for analysis.	

	• Developed AI technology to help assess quality of organ. • GP asked whether the images used will only be ones taken as part of clinical practice. CW confirmed that the images have been acquired for clinical purposes from previous donors. • EL confirmed that a DPIA for information sharing is in progress, working with information governance. There were no objections raised. ***Decision made: Attendees agreed that this study was straight forward could be granted approval with conditions, i.e. ensuring DPIA was approved.***	
4.3	**For Discussion Only:** Heart Biopsies • Luke Williams attended to present (luke.williams@nhsbt.nhs.uk) • Project looking at gene expression within transplanted hearts, with an interest in how we preserve hearts during transplantation and strategies for preventing primary graft disfunction. • Experimental design- 10 hearts (5 DBD & 5 DCD), needle biopsies. RNA sequencing for analysis of samples, which allows comparison of genes and gene pathways. • By comparing DBD and DCD hearts, specific differences between the two can be looked at, with the hope to identify pathways where we could intervene in order to improve outcomes. • Working in conjunction with QUOD. • Approved by CTAG (heart). • Funding approved by Papworth Charity. • MB added that the study would not affect the offering sequence, the retrieval or the NORS mobilisation. • GP asked to about the consent process and whether this would be from the donor families. LW clarified that, for donor families, this would come under QUOD consent and recipient consent would also be taken. GP reiterated that donor family consent would be required. • MS stated that there were operational considerations in that we would need to change the NHSBT SNOD SOP, as it currently says untransplantable hearts, therefore re-training for SNODs would also be required. Furthermore, if this document was to be changed completely, this could potentially be open to any transplantable heart biopsies, in which case a PDV would be required. VG confirmed that it would need to be restricted to hearts that were going to Papworth only, which could be managed and trained out. No decision required, as this was for discussion only.	
4.4	**Study 132:** Lung Ultrasound for Donor Lung Optimisation **RINTAG(22)5** RINTAG(22)5 Study 132 app form- Jas Pa Key points:	

	• Chief Investigator- Jasvir Parmar attended to present (jasvir.parmar@nhs.net), Jennifer Baxter (Jennifer.baxter@nhs.net) • Secondary Contacts- Ellen O'Brien (ellen.obrien3@nhs.net) • Proposed start date: 01.03.2022 (this date has passed, therefore ASAP from RINTAG/external approval), Study end date: 01.03.2024 • The study proposes to use bedside ultrasound to get better characterise lungs for transplantation. • JP explained that there would be a pilot study to look at feasibility, then move into interventional part looking at early donor management to improve organ utilisation. • The study has received funding and a team is in place, as well as a mobile ultrasound machine. • Awaiting REC/HRA approval. There were no objections raised. ***Decision made: Attendees agreed that this study was an important piece of work as it could directly impact on transplant numbers, therefore it could be granted approval with the condition to obtain other external approvals.***	
4.5	**Study 131:** The development of novel perfusion technologies and techniques for the treatment and assessment of kidneys to increase utilisation and improve graft survival **RINTAG(22)6** RINTAG(22)6 Study 131 app form- Sarah Key points: • Chief Investigator- Michael Nicholson (mln31@cam.ac.uk) and Sarah Hosgood (sh744@cam.ac.uk) • Proposed start date: 01.02.2022 (this date has passed, therefore ASAP from RINTAG/external approval), Study end date: 01.02.2027 • The study aims to obtain 300 kidneys over 5 years, using normothermic machine perfusion to look at increasing the quality and quantity being transplanted to make them last longer • REC/HRA approvals in progress There were no objections raised. ***Decision made: Attendees agreed that this study could be granted approval with conditions such as obtaining external approvals.***	
4.6	**Study 133 For Information Only:** Excluded in life: Included in death. Making the organ donation process more accessible for people with learning disabilities **RINTAG(22)7** RINTAG(22)7 Study 133 FOR INFO ONLY- Key points: • Project led by the Deputy Corporate Lead Nurse NHSBT, Bethany Hall (bethany.hall@nhsbt.nhs.uk)	

	• Start date: May 2022, Expected completion date: September 2022 • This project is a service evaluation using a quantitative questionnaire (Colosi, 2006), including both closed questions and Likert Scales to discover what resources would be required for a specialist nurse to adequately support and include a person with learning disabilities through the organ donation process. • The questionnaire will be sent to nurses within the national organ donation team who are involved in the process of supporting families through the organ donation process. This questionnaire aims to understand whether the organ donation team have experienced the need to support people with learning disabilities, whether they felt they had the resources and knowledge to do so, and if not, whether this impacted the person being included in the process. It will then explore what support and resources they would require in the future in order to be more inclusive of this group. There were no comments raised. No decision required, as this was for discussion only.	
4.7	**Study 135:** Factors influencing decisions to donate organs: Perspectives of the Specialist Nurse for Organ Donation **RINTAG(22)8** RINTAG(22)8 Study 135 app form- Debor Key Points: • Chief Investigator- Deborah Rickards-Hill (deborah.rickardshill@gcu.ac.uk) • Proposed start date: June 2022, End date: 01.08.2023 • The specific research objectives are to identify reasons most commonly linked to decision making in organ donation, through analysis of the donor audit data. • Asking for 3 years of donor audit data to identify demographics such as age, ethnicity, religious background, gender, geographical location and reasons provided for donation or non-donation. • Following this, approximately 12 Specialist Nurses would be asked to take part in an interview. • REC approval not required as this is a staff only project. HRA approval in progress. • LM raised that ODT CARE approval will need to be sought if national data is required, as it holds this data. There were no objections raised. ***Decision made: Attendees agreed that this study could be granted approval with conditions such as obtaining external approvals.***	
4.8	**Study 136:** Multi-modal assessment of liver grafts undergoing normothermic machine perfusion to stratify quality and deliver therapy **RINTAG(22)9** RINTAG(22)9 Study 136 app form- Gabrie	

	Key Points: • Chief Investigator- Gabriel Oniscu (gabriel.oniscu@ed.ac.uk) • Proposed start date: June 2022, End date: 20.06.2025 • The primary objective of this proposal is to investigate the use of a multi-modal approach for the assessment of liver graft quality and specifically individual cell compartments (cholangiocyte, hepatocyte). • The secondary objective: To investigate the use of normothermic perfusion for organ modification therapy. • 40 whole livers not suitable for transplantation would undergo normothermic perfusion during the three year period of the study. In addition, access to the national organ donation biobank (QUOD) would provide control tissue samples from organs that are transplanted and linked clinical data to establish correlation of the biomarkers with clinical outcomes. • HRA and REC approval not yet obtained. There were no objections raised. ***Decision made: Attendees agreed that this study could be granted approval with conditions such as obtaining external approvals.***	
5	**Resubmissions RINTAG(22)1 May 2022**	
5.1	**Study 24:** Kourosh Saeb Parsy request for tissue bank status **RINTAG(22)10** RINTAG(22)10 Study 24 Summary.pdf Key Points: • Chief Investigator- Kourosh Saeb Parsy (ks10014@cam.ac.uk) and Krishnaa Mahbubani (ktam2@cam.ac.uk) attended the meeting to present. • The study has been using tissue from deceased donors in Addenbrooks since 2012. This is not stored tissue, samples are taken for specific studies. • The study team take tissue themselves, therefore do not rely on NORS teams, but SNODs obtain consent specifically for study. • The current request is to change the approval so that the study is a research tissue bank. Received REC/HRA approval for this in June 2020. • KSP stated that there was no intention of storing tissue 'just in case', but only for existing collaborations. • GP asked whether there would be one consent form or two. KM explained that the consent form would be different (switching from original consent form to a new one), with explicit restrictions. MS raised that we have previously used consent form stickers and documented specific consent on the NHSBT consent form. MS also stated additional training would be required for the SNOD. KSP confirmed that each family will only be given one participant information sheet and one consent form, which will replace the existing study consent form. There are only two information sheets due to there being slightly different information on both that was discussed with the REC, but only one will be used.	

	• MS asked how the SNODs will know which consent form to use. KSP stated that, when a potential donor is identified, SNODs usually call the research team to see if they should consent them. At this point they would be told which to take consent for. • AF raised concern around how this arrangement relates to the existing arrangements through INOAR, i.e. if consent was through INOAR for a RINTAG approved study, how this study interrelated to that. KSP confirmed that there would be no overlap between this study and INOAR, as they do not take samples from any organs that have been retrieved for transplantation. KM stated that this is where communication with the SNODs is important. • VG asked for clarification about changing ethical approval to a research tissue bank, which meant the research team were no longer responsible for the tissue, which raised concern around end-to-end accountability. KM explained that end-point users would need to have their own ethics approvals, therefore their own responsibility for the tissue. Any research restrictions would be passed on to users. • GP stated that there was an issue with transparency from an NHSBT perspective in terms of appropriate observation of restrictions. KP explained that annual returns are submitted and letters written to families about what tissues are used for. KM agreed to set up a system to share so that NHSBT have oversight over where the tissues are going. ***Decision made:*** ***Attendees agreed that this study could be granted approval, but with the conditions that the team continue working with the ODT research team in addressing the outstanding operational issues. The researchers would also need to develop a process by which a summation of tissues retrieved via this study, and their research outcomes, would be submitted regularly to NHSBT.***	
5.2	**Study 63:** Transplanting the untransplantable- extending antibody incompatible transplantation using a normothermic perfusion model with cytoprotective agents **RINTAG(22)11** RINTAG(22)11 Study 63 Resubmission forn Key Points: • Chief Investigator- Nizam Mamode (nizam.mamode@gstt.nhs.uk) • Secondary Contacts- Pankaj Chandak (pankaj.chandak@nhs.net) • Additional 10 kidneys were requested in the last re-submission, which brought the total to 30. Now requesting another 15 which brings the total to 45. • Study duration lapsed- requesting new end date of 01.04.2024 • Request to add vascular endothelial cells at the end of the current human kidney EVNP model, to determine if they integrate into the renal vasculature and promote endothelial healing post-antibody mediated rejection induced injury. There were no objections raised. ***Decision made: Attendees agreed that this resubmission could be granted approval.***	

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5.3	**Study 88:** An initial evaluation of ex vivo senescent cell depletion as an intervention to improve the long-term function of kidney transplants **RINTAG(22)12** RINTAG(22)12 Study 88 Resubmission forn Key Points: • Chief Investigator- David Ferenbach (david.ferenbach@ed.ac.uk) • This study had been delayed by a combination of Brexit related complications which delayed the arrival of appropriate perfusion machines, and Covid19 related lockdowns leading to the inability to run research studies (and indeed clinical transplantation). As the study was last approved by RINTAG in 2020, a new submission was required. A new study end date has been set for 30/06/2024. There were no objections raised. ***Decision made: Attendees agreed that this resubmission could be granted approval.***	
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5.4	**Study 90, 91 & 101:** Quality in Organ Donation: QUOD-MRC – Expansion to include Whole-Collection and Research of Heart, Lung, Pancreas, Kidney and Liver **RINTAG(22)13** RINTAG(22)13 Study 90 91 101 Resubmiss Key Points: • Chief Investigator- Rutger Ploeg (rutger.ploeg@nds.ox.ac.uk) • Secondary Contacts- Emma Greig and Sarah Cross (contact@QUOD.org.uk) • Study duration lapsed- not yet received all of the organs requested in application. Request to extend the study to 31.03.2024. • Mistake on RINTAG ranking document under the "Evaluates novel technology/ies in organ transplantation" column. This column should say yes. There were no objections raised. ***Decision made: Attendees agreed that this resubmission could be granted approval***	
6	**Statistics**	
6.1	**Research Consent/Authorisation Rates RINTAG(22)14** Please see paper for full details, but key points: • In 2021, only 7% of actual solid organ donors had no research consent or authorisation, slightly up on previous years, with the highest being in Scotland (96%), compared to Wales (92%). • For organ specific consent for actual organ donation, where donors have given research consent, the majority of those where research consent was given, the family also gave consent for kidneys, livers for hepatocytes and livers at around 90%. The lowest was bowel, with only 20% consenting. • For tissue specific consent, the consent rate is quite low for organ donation where research consent was given, blood vessels was the highest at 92%.	

	• In terms of research consent status, its still relatively high overall at 93% in the UK. RINTAG(22)14 Research consent Ma	
6.2	**Availability of Organs for Research** **RINTAG(21)15** Key points: • In 2020 we saw a drop in the number of organs that were retrieved for research due to COVID, with a number of 299. In 2021 this has risen again with 451 organs used for research, 354 disposed, and 34 where there was no generic consent and they were disposed. • 54% of all organs taken for research were used for research, which is the highest we've seen since 2017. • 17 hearts were used for research and 31 lungs, which is the highest seen in the last five years. • 119 livers taken for research, slightly lower than 2019. Kidneys 202 taken, pancreases 82 taken. • 511 organs were offered through the National Allocation Scheme, 254 were accepted. • GP and EL commented that it would be useful to explore the reasons why organs are not accepted for research and being disposed of, i.e. time of day the offer goes out. LM stated that this was looked at previously and offers out of hours was the biggest reason for non-acceptance of research organs. AF commented that we should strive to increase the utilisation rate of organs, however we also need to be mindful about the challenges, i.e. studies not having the resources to staff for 24 hours. • GP stated that we could begin to look at what organs are preferentially sought. • MK commented that it would be useful to identify the impact of not having clarity on specific definition, i.e. genetic and animal research, on not being able to utilise organs for research. RINTAG(22)15 Research availability M	
7.	**Ranking Working Group Update** • GP gave a brief update on where the ranking group is. It was indicated that the previous algorithm was not suitable and we ended up with artificial distinctions between different studies. • There is a need to simplify the process and consider rotating studies so that no single study was always given priority. • Currently working through how this might look, but there are 4 broad categories: - Studies involving transplantation - Studies that increase utilisation (longer term) - Basic science - Studies that do not involve transplantation • Input is required from other teams, i.e. the Hub, Statistics.	

	• MK commented that judging the time for research to be translated into the clinical setting would be controversial, as this is the point of research. GP stated that having the studies categorised into the four groups and with more rotation, this should help with that. • Other elements to consider are geography and number of organs requested. • Once a new process has been developed, this would be brought to RINTAG for wider consultation. • AF suggested considering studies who can work together to share materials and rotating studies on a weekly/monthly basis, which would help with planning from the researcher's side. EL mentioned that we would need to consider end to end traceability if organs were to be shared. • EL assured the group that ranking is not always needed to be referred to for every organ offer, as often only one study will ring in to accept the offer. Ranking is only used when more than one study show interest**.**	
8.	**INOAR**	
8.1	**Update RINTAG(22)16** Please see paper for full details, but key points: • Paper taken to Retrieval Advisory Group on increased number of organs available for research that was implemented in January 2021. • Since the 1st February 2021 to 30th April 2022, 328 organs were offered via INOAR, of which 148 were accepted for research, 97 were removed and 51 organs not removed. • Hearts- 170 were offered for research, 36 were accepted, 23 removed, 13 not removed. • Lungs- 100 were offered, 64 accepted, 36 removed, 30 not removed. • Diabetic Pancreas- 68 offered, 42 accepted, 38 removed, 9 not removed. • Pancreas has highest utilisation rate, followed by lungs. RINTAG(22)16 RINTAG INOAR paper	
8.2	**Focussed Discussion on Hearts:** • Hearts have been the least accepted. A stakeholder engagement meeting was held with heart researchers to look at the barriers. It was found that cold ischaemic time was having an impact, in particular when it is an abdominal retrieval only. • Last year we saw a reduction in the number of CT retrievals which had a significant impact on the number of hearts accepted for research. • It was found that a large number of hearts were being accepted for transplant but deemed unsuitable at the point of inspection and we are not in a position to offer those hearts that are deemed unsuitable at the point of retrieval • Options have been considered to increase the number of perfused and packaged hearts removed for research via INOAR: - Abdominal NORs teams are trained to perfuse and package hearts removed for research studies in the absence of a CT NORS team. - Implementation of a second offering point for INOAR when hearts accepted for transplant, unsuitable for valves are declined for transplant in the donor theatre on investigation/ inspection. Cardiothoracic NORS in attendance.	

	- Researchers +/- NORs off duty surgeon attend donor theatre to perfuse and package heart removed for research study. • DH asked whether there was a risk of cerebral perfusion using the heart perfusion technique that will need to be mitigated. IC explained that, in the DBD scenario, the patient is brain dead and they would be cannulating the aortic arch in the same way that the CT team would do. In the DCD scenario, it would be perfused with University of Wisconsin (UW) Solution, not blood. Therefore, there isn't a scenario where the brain is perfused with anything other than UW.	
9.	**QUOD Report RINTAG(22)17** Please see papers for full details, but key points: • From 1st April, up to 6101 donors. • Collected 113.137 samples (see breakdown in paper) • No incidents from liver biopsies • Low number of incidents in kidneys in 2021, nothing yet this year. • Dip in consent during COVID 2020/2021, but consent rates are going back to normal levels between 85 and 90%. • Supplied 33,021 samples to researchers. • AF raised that bronchoalveolar lavage (BAL) samples are still very low. SC explained that this was limited during COVID, but all restrictions have now been lifted so this will resume. One Possible issue is that NORS teams do not know that BAL samples should be collected for QUOD. We, therefore, may need to consider training for CT/Abdominal teams. IC stated that SNODs could remind teams to take the samples.  RINTAG(22)17 QUOD Statistics - Exte	
10.	**Clinical Governance Update** There was no official Clinical Governance Update available at today's meeting. But points discussed: • EL explained that there was a risk of bleeding when NRP is initiated when removing CT organs. General consensus at the time was that we would withhold removing organs only for research, the risk would only be taken where there was a clinical need. There is a process deviation in place where we are not able to offer CT organs for research until we are able to mitigate the risks of NRP. EL stated that there had been an incident where there was a deviation from this and organs were removed for research when NRP had been initiated. This is currently under investigation by the clinical governance team, and an update should be available at the next RINTAG meeting.	
11.	**AMD Update** LMa gave verbal update. Key points: • New appointments -Richard Baker -Sanjay Sinha, surgical lead for governance -Chris Callaghan and Diana Garcia national leads in organ utilisation • Board set up for all AMD's, meeting monthly. Working on the implementation of the OUG recommendations once they are out (expected in August)	

	• Launch of new BTRU in Newcastle and Cambridge for transplantation • Five projects submitted by OTDT for funding consideration to NHSBT R&D. • Will be advertising for a Clinical Research Fellow to undertake work nationally around patient reported outcomes and experiences, also working in collaboration with the BTRU.	
12.	**Non-transplant related research prioritisation (NODTRR) RINTAG(22)18** Please see paper for full details, but key points: • There are increasing requests from research teams focused on questions which do not directly relate to organ donation or transplantation. These include access to donors, donor families and/or organs or tissues that could be retrieved at the time of organ donation during donor management or during/after the retrieval operation. • Recognised the need for an agreed policy/guidance on how such requests should be considered and prioritised. • Suggestion at previous meetings was to encourage researchers to come forward with proposals early which would be given outline support for, then they would come back for full RINTAG review. • EL asked that, when there are researchers getting access to organs, these are ones that are discarded, as we do not want to put any extra pressure onto the Specialist Nurses having to ask for specific consent for organs or tissues that are non-transplant related. DH suggested adding education, training and capacity to the document so that there is a realistic expectation of what could be delivered. • DH asked whether this should be a guidance document or a formal document. LA stated that the document should be available on the website so that we are transparent. VG indicated that we could have the document available on the microsite without it being a formal policy, it would just need to be managed and reviewed. RINTAG(22)18 NODTRR Discussion F	
13.	**CTU – Update RINTAG(22)19** Please see paper for full details, but key points: • **SIGNET**- 67 out of 77 Trusts open with SNODs playing key role consenting donor families. There are high rates of approach and consent. • **PLUS**- this is a study on high risk DBD and DCD livers, exploring the impact of NMP on outcomes. Opened recently across all 7 UK transplant centres. Hub heavily involved in ensuring there is awareness of when the liver is eligible for the intervention. • **COBALT**- opened in Cambridge and Oxford, four sites still in set-up. Two participants have enrolled and completed their baseline assessments. • **DeFat**- in set-up phase and has been submitted to the REC/HRA. Paperwork was submitted too late to be considered at this RINTAG meeting, but an overview of the study was given (please see details in paper). • **PLUTO**- recruiting extremely well, due to finish in the next few months. • **PITHIA**- now closed to recruitment. • **MELODY**- not mentioned in the paper. This is a COVID-19 study looking at immunosuppressed populations to see how they had responded to the COVID-19 vaccinations.	

	RINTAG(22)19 CTU for RINTAG 2022 05	
14.	**Research Restrictions Definition** Key Points: • EL shared INF1374 (SNOD frequently asked questions- animal, DNA and commercial research studies definitions) which was reviewed and approved by ODT CARE and seen by over 240 stakeholders for input. However, we are receiving feedback from researchers and Specialist Nurses about ambiguity and language used. There have been inconsistencies with how the definitions are applied. • Language too complicated, therefore Specialist Nurses are not confident having conversations about research restriction definitions with donor families. • Steady increase in the number of donor families who are placing restrictions on the consent given for research, primarily animal research. • Work required to amend information leaflet and to upskill the Specialist Nurses to enable them to feel confident having this discussion. • GP commented that the blanket restriction based on institutions and their animal use is illogical and that we should move away from that. • JH asked how much involvement donor families have had in explaining what concerns they may have over organ/tissue restrictions. EL stated that there wasn't as much patient and public involvement previously as there should have been. Therefore, the plan would be to involve patient and public advisory groups and SNODs. • DH stated that accessing a broad range of donor family opinion for such work can be difficult in terms of speed and cost. There could be some broader questions about research activity and donor families that could be asked in a formal research project, but this would not stop us from amending the current guidance. • MK asked whether it should be our responsibility to draft something simple and then go for consultations with the advisory groups. DH commented that our own researchers and collaborators have different interpretations of the definitions, therefore agreed that this needs to be lined up before wider consultation. MK suggested putting together a small multidisciplinary group to come up with simple definitions, then bring them to RINTAG for discussion, then seek patient and public opinion. DH stated that wider consultation had been done before without a problem being spotted, however a small working group would be a reasonable approach.	
15	**What requires RINTAG approval? Discussion** • There had been a number of discussions around what requires RINTAG approval or not. HT asked whether submissions required approval or whether some are just for information only, i.e. projects that have been peer reviewed, funded, gone through the REC and have no operational impact on NHSBT. • LMi commented that what does come to RINTAG does not necessarily translate into immediate operational action. There needs to be a process where we map the project out to see what teams are impacted and any training, i.e. for SNODs. Therefore, there needs to be an appreciation that, after RINTAG, there are processes that need to be adhered to before a study can go live.	

	• EL stated that we have received a clear steer from the HTA recently about when it is no longer considered the donor organ and is the recipients'. It is important to safeguard the donors and ensure the correct consent is in place, which would be something that RINTAG consider. EL commented that anything that is interventional, novel therapy or involves the donor until it is implanted into the recipient should come for approval. • VG indicated that the steer from the HTA states that, up until the point of implantation of an organ, if material is to be used for research, it will require donor consent according to the Human Tissue Act. Therefore, this should be formalised into a position or policy statement for RINTAG to follow. DH commented that other regulatory bodies should be involved in these discussions to, in order to ensure alignment, i.e. the HRA/REC. IC commented that, from the recipient side, we should be more general, in that it is more likely that organs would have been biopsied than previously. Therefore, there should be a general acceptance that all consent processes on the recipient side should formally mention this. VG stated that the Human Tissue Act is heavily slanted towards safeguarding against misuse of deceased donor tissue. Therefore the rules for taking tissue from the living recipients are slightly more relaxed in terms of consent and anonymisation. It would be expected that the HTA would require donor consent for that reason of making sure tissue doesn't get used in research if a family wouldn't have agreed. • GP commented that RINTAG is here to be helpful in working with researchers as early as possible and recognising any potential problems, rather than act as a barrier to research. **ACTION: VG to go back to the HTA to get a clear statement regarding consent and when the organ/tissue becomes the recipient's, also liaising with the HRA/REC. This can then be used in a policy statement to inform RINTAG and circulate widely.**	
16.	**Any Other Business** There was no other business for discussion.	
	Date of next meeting: 01 November 2022	