RINTAG(M)(17)1

NHS BLOOD AND TRANSPLANT
ORGAN DONATION AND TRANSPLANTATION DIRECTORATE

RESEARCH, INNOVATION AND NOVEL TECHNOLOGIES ADVISORY GROUP

MONDAY 15 MAY 2017 – 10:30 – 15:30

COUNCIL CHAMBER, THE ROYAL COLLEGE OF ANAESTHETISTS, 35 RED LION SQUARE, LONDON WC1R 4SG

Present:

Gabriel Oniscu	GO	Chair
Hazel Bentall	HB	Lay Member
Anthony Clarkson	AC	Assistant Director for Organ Donation & Nursing, ODT
Andrew Fisher	AF	NIHR BTRU
John Forsythe	JF	Associate Medical Director, ODT
Peter Friend	PF	Chair, Bowel Advisory Group
Victoria Gauden	VG	National Quality Manager
Rachel Johnson	RJ	NHSBT Statistical & Clinical Studies
Sally Johnson	SJ	Director of Organ Donation & Transplantation
Maria McGee	MMG	ODT Research Project Manager
Elizabeth Murphy	EM	Lay Member
Rutger Ploeg	RP	Chair, National Retrieval Group, Director of QUOD
Maggie Stevens	MS	Specialist Nurse Research & Service Delivery
Steven Tsui	ST	Chair, Cardiothoracic Advisory Group
Nick Watkins	NW	Assistant Director – Research & Development, NHSBT
Chris Watson	CWa	Chair, Kidney Advisory Group
Claire Williment	CWi	Head of Transplant Development, ODT

Apologies:

Dave Collett	NHSBT Statistical & Clinical Studies
Rachel Hilton	BTS Representative
David Metcalf	NHSBT, Finance
John O'Grady	Chair, Liver Advisory Group
Karen Quinn	Assistant Director for Commissioning, ODT
Michael Stokes	Duty Office Manager, NHSBT
John Casey	Chair, Pancreas Advisory Group
John Dark	National Clinical Lead – Governance

In attendance:

Heather Crocombe	HC	Clinical & Support Services

		Actions
1.	**Welcome and Apologies** GO welcomed everyone to the meeting and gave details of apologies (shown above)	
2..	**Declarations of Interest in relation to the Agenda** JF expressed concern that RINTAG's conflict of interest table was	

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	incomplete. It is crucial that advisory group members declare any conflicts of interest as a matter of urgency, or the validity of the Group would be compromised. If members fail to provide full declarations of interest they may not be invited to participate until these had been provided. ***(Action 1) HC to re-circulate declaration of interest form and table. All members to review and amend where appropriate.***	HC – Action completed
3.	**Minutes of the Research, Innovation and Novel Technologies Advisory Group Meeting held on 8 November RINTAG(M)(16)2** The Minutes of the meeting held on 8 November 2016 were deemed to be a true and accurate reflection of that meeting, except: CW asked that page numbers be added, attendees be listed on page 1 of the Minutes rather than the last page, and formatting is checked and amended where necessary when points are removed. **Action Points from the Research, Innovation and Novel Technologies Advisory Group Meeting held on 8 November RINTAG(AP)(16)2** 11. *Arrange a phone line without "No caller" ID, to ease the new offering process.* Update required from Mick Stokes. Keep as an action. ***(Action 2)*** 20. *GO to raise the issue of blood utilisation for ex situ perfusion and preservation technologies at NRG and will seek advice from Sarah Morley on the blood team.* GO has raised the matter at NRG – advice from SM to be sought. ***(Action 3)***	HC - Action completed MS GO
4.	**Research Activity (RJ) RINTAG(17)1** RJ presented RINTAG(17)1, summarising the demand and use of organs for research. It showed the number of retrieved organs and the potential organs available for research following the 20th February introduction of Research organ allocation. Research organs are now allocated to the highest ranked study that responds within 45 minutes. RJ advised that after speaking to Duty Office, their perception is that most studies do not respond "out of hours" and this is obviously going to influence where organs are placed. This could be deemed to be unfair, but it was noted that this was the case before the introduction of the new system and that it was the duty of the researchers to respond to calls within the agreed timeframe. The allocation policy may therefore not influence or improve this. RJ was unsure how many units have been responding within 45 minutes but can look at these data – having this information to hand	

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	will improve data collection as a whole and provide a more rounded picture. ***(Action 4)***	RJ
	It was clarified that offers are made by a simultaneous text, with the organ going to the study that accepted and had the highest ranking.	
	GO and MMG will ensure researchers state in the progress report reasons why offers aren't being accepted. ***(Action 5)***	GO/MMG Completed
	The issue of transport needs to be considered when centres turn organs down. AF gave an example of an organ which was offered to Newcastle which, had they accepted it, would have been outside the body for some 20 hours and the condition of the organ would have deteriorated to the point where it became unusable. This was purely down to the distance the organ would have needed to travel.	
	It was agreed that the Research Project Team should monitor imminent end dates on a quarterly basis, and contact researchers whose study is due to come to a close to seek clarification regarding whether the close date needs to be amended and if so, why.	
	RP asked, if there is no activity on a project for a certain period of time, does this mean that the project goes 'down the ranking' or remain as is? This is to be discussed further, at the next RINTAG meeting. ***(Action 6)***	HC to add to agenda
5.	**Activity So Far** **5.1 RINTAG Research Review Jan 2016 – Apr 2017 RINTAG(17)2**	
	MMG presented paper RINTAG(17)2, giving details of all RINTAG research activity since January 2016.	
	Members agreed the provision and level of detail of data was helpful and should continue to be presented at RINTAG in the same format, with the exception that all comments made should be kept confidential.	MMG
	5.2 RINTAG Application and Approval Processes Jan 2016 – Apr 2017 RINTAG(17)3	
	CWi explained that the ODT Research Project Team's remit is to support research and ensure that applications are reviewed, approved and go live as quickly as possible. To support this aim, data on timescales from initial application to RINTAG to approval to go live has been collated. These data are still in a raw state and yet to be analysed in detail.	
	However, in the majority of cases, studies were brought live within four months of application submission – however, timescales vary	

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	greatly between cases. Work is under way to investigate the reasons behind this and to identify where improvements can be made. AF said we are very grateful for all the work put into looking at this process and how it can be improved and streamlined. GO thanked MS, MMG and CWi for the work they have done on this. CWi has met with the HRA and agreed a greater level of collaboration to minimise requirements for researchers and streamline the approvals process. This work would continue and be reported back to the Group. The Group noted that this should not delay work within NHSBT and RINTAG to minimise bureaucracy. RP made the point that we also need to clarify exactly which 'steps' of the process are to be completed by NHSBT and which are the responsibility of the researcher. *HTA Regulations on Research Licences.* AF said this is a real issue at the moment and the cause of a 'postcode lottery'. It uses up a huge amount of an investigator's time. Members agreed that NHSBT should be asked to work with the HTA to clarify and improve the licensing processes. These processes vary in different parts of the country and cause a significant amount of work and confusion for both researchers and NHSBT. RINTAG would be happy to support any negotiations.	
6.	**Allocation of Organs for research – Initial Research Organ Allocation Scheme RINTAG Feedback RINTAG(17)4** MMG presented RINTAG(17)4, outlining the review of the impact of the range of new policies and approaches introduced to improve the research processes. The Research Project Team keeps all amendments under review and seeks comments from researchers and other stakeholders about where improvements could be made. The paper provided a summary of relevant feedback and suggested amendments to those policies and processes. The following amendments were raised: <u>Assessment Criteria</u> Point 2: Remove the assessment criteria *"NHSBT resources required to deliver"*. Members agreed. Point 3: *Amend the assessment criterion for: impact on donation, retrieval and transplant processes*. Agreed. Point 4: Amend the wording *"transplant units"* to instead be	

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	"transplant units and/or educational institutions". Members decided wording should be *"transplant units and/or research groups"* and not *"educational institutions".* <u>Additional Prioritisation Criteria</u> Point 2. *Ensure studies which have been awarded funding with required grant milestones do not lose their funding due to the matrix design.* The group advised that this could lead to 'gaming' of the system. A better approach would be for the Research Project Team to work closely with the researchers at an early stage to understand their requirements and manage expectations. AF asked how we can be sure that researchers have been honest on their applications – it is a concern which might be resolved by RINTAG being much more involved with researchers drafting their applications. ODT encourages prospective researchers to engage early. This is something that needs to be looked at further. Point 3: *Design the allocation system such that organs/tissues can be allocated to another study after initial use.* GO asked whether RINTAG is happy to introduce a tick box function, giving researchers the option to forward on organs once they have completed using them? JF made the point that in that case, transport costs must be borne by the receiving unit. If this is introduced, we need to talk to Quality Assurance and Duty Office (to ensure that families' consent extends to this) and to ensure that this is operationally feasible. <u>Prioritisation Requirements, Two Tied Projects</u> Currently in the SOP4442, in cases of two tied projects accepting an organ, allocation is made to the closest unit geographically. The decision was made to monitor the frequency of this occurrence and take those findings back to the next RINTAG meeting. Consultation will be required with the Duty Office.	
7.	**Research Application Process and Website Visibility** 7.1 <u>Handbook and Application Form Template</u> **RINTAG(17)5 & RINTAG(17)6** The new Handbook has been prepared and is now in use. RP made the point compiling the handbook has been an awful lot of work, and work which has been very well done. On p5. of the handbook, does another category, category 7, need to be added for "QUOD"? MMG will amend to include this. ***(Action 7)***	MMG – Completed

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	GO queried Category 3, where there is a requirement for proof of funding for university studies but not for NHS Studies. MMG advised that these requirements are different as non-NHS site studies in England (including universities) are exempt from HRA assessment. MMG will cross-check the accuracy of this. ***(Action 8)*** 7.2 <u>ODT Research Registry – Current Status</u> **RINTAG(17)7** • Re-submission to RINTAG is required in the following scenarios, where continuation is required: a. If a study has received the number of organs initially requested and/or; b. the study duration has lapsed, and/or; c. further organs are required d. new objectives / REC extension Researchers will need to justify why the number of organs requested and/or received during the study duration wasn't sufficient. • Some studies currently active were approved pre-RINTAG with vague requirements outlined in the submission. Work is underway to collate and update organ requests and study durations ***(Action 9)***. • CWi asked if the regularity of the review process should be looked at (currently carried out quarterly). After some discussion, the Group decided that this should remain as is, until the 6 months evaluation. • "Number of Organs Received" will be updated every 6 months on the website in line with collated progress reports from researchers. • The Group was asked to consider a grace period for scenario B above. No decision was reached. The Research Project Team suggests a pragmatic approach be adopted by allowing up to 5 abdominal organs or; 2 CT organs and/or; an additional 2 months be granted without requiring additional RINTAG approval.	MMG – Completed MMG – In progress
8.	**Sub-Group Updates – *Increasing Number of Organs for Research*** **INOAR** **Increasing the Number of Organs Available for Research** INOAR was established to consider ways to address the shortfall between the number of organs required for research (approx. 1600 p/a) and the number of available organs (approx. 540 p/a). The remit of INOAR is to review UK legislation and ethical frameworks, together with UK policies, guidance and clinical	

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	practice relating to obtaining organs for research. The first meeting had been held and work was underway to review what could be done to utilise current licensing arrangements to better effect, as well as make improvements to the research care pathway. PF made the point that huge numbers of lungs do have research consent, but assessment of lungs doesn't allow for the removal – it's done in situ. To access these, a massive change in clinical practice would be required and this might not be achievable.	
9.	**Studies for Approval and Information RINTAG(17)8** *Training Model for Robotic Kidney Transplantation* This paper was presented to the meeting for advice. It was agreed that: The Group endorsed the request in principle, under the following conditions: Request 1: "*To access the vessels (iliac arteries and veins) coming to our hospital with an SPK (pancreas kidney) offer in cases we don't use the organs and they are going to be declined by all centres and discarded".* Condition: RINTAG lends its support to this request conditional upon assurances of traceability, consent and if the relevant storage licensing requirements are in place. Request 2: "*To access vessels accompanying organs for transplantation (any organ) in any other centre in cases the transplant didn't proceed and organs will be discarded".* Condition: RINTAG supports this request. However, it is your responsibility to contact the transplant centres and arrange packing and transportation of relevant material and comply with the assurances highlighted above. For this approach, you will be required to submit an application to be ranked in the research allocation scheme. Request 3: "*To access vessels that are stored in vessel banks for clinical purposes but if not being used after sometime again they will be discarded"* Condition: RINTAG lends its support to this request conditional upon assurances of traceability, consent and storage licensing requirements. It is your responsibility to contact the relevant vessels banks and request access to the material. Copies of the completed application form and other submission details/ documents is required to facilitate RINTAG's final assessment, including the confirmation of operational support. *Pre-Implantation Trial of Histopathology in Renal Allografts*	

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	This paper was presented to the meeting for information. No issues were raised.	
10.	**Horizon Scanning** GO proposed this as a standing item on each RINTAG agenda – to discuss anything new or exciting. The following topics were raised: • Enable licensing approach and licencing of devises • NIHR Innovation Observatory in Birmingham, emerging technologies • Decellurisation/ recellurisation tissue • Government Office for Innovation • Bioprinting, Blood donor stratification • Centralised delivery of healthcare	
11.	**Defining Perfusion Ischaemic Time** RJ advised that NHSBT Statistics and Clinical Studies have submitted a request to add "donor end" data to the form currently in use. RJ advised that additional resource will be required if we are to integrate data. RJ added that Statistics have taken on work on a number of ad hoc data forms recently (eg Kidney record form, Pancreas record form) which has added to their workload. A letter should be sent from RINTAG to all transplant units using novel technologies requesting the surgeon to record the data (ODT number) in the interim. ***(Action 10)***	GO/MMG
12.	**Olfactory Bulbs and Uterine Transplant Update** <u>Olfactory Bulbs</u> MMG and MS have been working with teams to gather information. St. Georges have decided to put this on hold for the moment until a new research fellow is appointed in the autumn. Birmingham is still in the early stages of the process. In the meantime, the NHSBT Communications Team will be in touch with the relevant hospital Communications Teams to agree a strategic plan, to be included in respective protocol. <u>Uterine Transplant</u> The HRA and R&D application is yet to be filed. The Executive support letter from Oxford is still outstanding. PSSAG approval has been obtained by NHS England. However, there is no expectation from the research team of future	

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	commissioning at this stage. The whole project is funded by a Charity. The NHSBT Commissioning Team, NHS England, the Sponsor, the ODT Research Project Team and the researchers are due to meet on the 30th May. The project requires final approval by ODT SMT.	
13.	**Service Evaluation Update** EVLP – This service evaluation has been stopped. NRP – A Business Case is underway for NRP work within the UK. DCD Hearts – A DCD Hearts Steering Group was set up to look at retrieval and outcomes between Harefield Team and Papworth Team. This included outcomes of liver and pancreas retrieval with previous report circulated to RINTAG. Comparison report (between DBD and DCD) has been written up with a view to submit to The British Medical Journal soon. Discarded Pancreas Audit – A significant number of pancreases are currently being discarded (about 35%). This information has been taken to PAG. To help reduce discard numbers, a series of videos have been made and will be circulated to every pancreatic surgeon in the country. This will hopefully prompt a better understanding of 'risk' taking attitudes in different centres.	
14.	**QUOD Report** Please see papers below. In summary: • A one day meeting is held each year to include all QUOD partners. • Consent numbers are quite good and RP said he wants to give his thanks to the SNoD leads for this. • Out of 100% agreed for transplant, 89% also gave consent for QUOD research projects • Most teams are very good in obtaining samples. • Oxford was the first unit to start research using samples, however several other partner units across the country have now joined in with this.  Research projects.pdf  QUOD RINTAG Report.pptx  QUOD RINTAG Report Application tra	
15.	**Islet Labs** There is an issue of islets utilization for research after isolation for clinical transplantation which does not proceed due to low purity or number of cells. The islets labs feel that they have ownership of	GO to report back at next

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	these islets, particularly as they incurred the costs of isolation. Furthermore, there is a different and strict governance process for the islets labs. A way forward to allow access to the islets for NHSBT supported projects needs to be agreed. GO is looking into. ***(Action 11)***	RINTAG meeting
16.	**Any Other Business**	
	Date of next meeting: 10.30am, 9 October 2017, The Association of Anaesthetists, 21 Portland Place, London W1B 1PY	
		May 2017

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