APPENDIX 2 - Working examples
NHSBT ODT Research Study Categories

Category No.	Category title	Ref.	Description	Working examples
1	**Data study**	DS	Studies with a pure statistical focus, not requiring access to relevant material e.g. undertaking analysis of existing data on transplantation	**Name:** *Cancer risks from medical radiation exposures - impact of organ transplantation on associated cancer risks* **Aim:** *Researching the cancer risks from computed tomography (CT) scans and cardiac catheterizations in children and young people (under 22 years). The team have established respective cohorts of individuals who have had these procedures, estimated their radiation doses and matched members with the NHSCR to determine who has developed cancer. The research team would like to know who, from a list of NHSBT cohort members, has received a transplant, the organ involved and the date of transplant. Initially, propose restricting only to our smaller cardiac cohort as the CT cohort is very large.* **Approvals**: *REC, CAG[1] and NIGB[2] approvals. Shared with RINTAG for awareness. Application managed by the NHSBT Stats team.*
2	**Qualitative study**	QS	Studies with a descriptive or behavioural focus, not requiring access to relevant material e.g. examining attitudes toward organ donation, including the participation of donor families or	**Name**: *Mind the Gap: Exploring the differences in UK consent rates from the perspectives of the Specialist Nurses Organ Donation* **Aim**: *To explore what the experts working in the field view as the key factors that contribute to the different consent rates between the DBD and DCD in the UK*

[1] Confidentiality Advisory Group
[2] National Information Governance Board for Health and Social Care

			SNODs	**Approvals**: University ethics, *RINTAG for awareness. Application managed by the NHSBT R&D Office.*
3		BS	Studies looking to access blood, urine and tissue samples from deceased organ donors. Facilitated via the national biobank resource Quality in Organ Donation (QUOD). Samples are collected at four different time points covering the donor management period, all the way through to the point of organ retrieval	**Name:** *Investigation of transcriptional signatures predictive of suboptimal short- and long-term outcomes in deceased circulatory death kidney transplants* **Aim:** *To measure the expression of genetic information in kidney biopsies using a method that can read-out hundreds of thousands of genes. To subsequently select a small number of markers from this big group that best associate with bad or good outcomes.* **Approvals:** *QUOD Steering Committee. Other approvals as required*[3] *Application managed by the QUOD team.*
4	**Study on organs deemed untransplantable following removal from the donor**	UR	Requesting access to solid organs by generic research consent/ authorisation[4] i.e. organs that are removed from the donor for the purpose of transplantation but are subsequently deemed unsuitable for transplantation. Organs are offered via the NHSBT Duty Office to approved studies. RINTAG prioritises and ranks approved research studies.	**Name**: *Exploring the structural and functional effects of normothermic machine perfusion and de-fatting agents on human steatotic livers.* **Aim**: *To investigate the effects of normothermic machine perfusion (NMP), with and without de-fatting agents, in the preservation of steatotic human livers through structural and functional liver assessment.* **Approvals**[5]: *REC, RINTAG. Application managed by the ODT Research Facilitation Team.*
5	**Study on organs**	RR	Studies proposing to retrieve relevant material from donors,	**Name**: *Improving Transplantation outcomes by investigation of novel methods of organ procurement,*

[3] The QUOD biobank holds generic ethical approval for research projects concerning improving quality in organ donation. Additional local approvals may apply.

[4] The Human Tissue Act 2004 (England, Wales and Northern Ireland) specifically uses the term *'consent'*, whilst The Human Tissue Act 2006 (Scotland) uses the term *'authorisation'*.

[5] This is an example of a study taking place at a University, non-NHS site, in England and is exempt from HRA assessment

	removed specifically for research		purely for research purposes i.e. require specific consent/ authorisation from donor families, in addition to normal consent/ authorisation. Studies in England, Wales and NI require HTA licensing considerations, according to the Human Tissue Act 2004.	*preservation and reconditioning. Further Evaluation of Ex Vivo Lung Perfusion to Improve Transplantation Outcomes* **Aim**: *The strategic aim is 'to develop and evaluate novel approaches and technologies that increase the availability of suitable donor organs for transplantation, while improving graft survival'. To establish a robust experimental system for the evaluation of donor organs. We propose to utilise the substantial number of UK unused donor lungs to evaluate the currently accepted physiological EVLP assessment criteria alongside novel physiological, biological, ultrastructural, radiological and microbiological assessment tools performed during EVLP. Our aims are firstly to find improved indices and biomarkers of donor lung viability and future graft function that will allow increase the conversion rate to transplant for extended criteria donor lungs.* **Approvals**: *REC, HRA, RINTAG, NHSBT operational written confirmation. Application managed by the ODT Research Facilitation Team.*
6	**Donor intervention study**	DI	Studies looking to undertake interventions in DCD donors prior to death[6], and/ or interventions to DBD donors i.e. drug administration to facilitate organ preservation.	**Name**: *An evaluation of the physiological changes of circulatory-determined death with respect to organ donation and transplantation* **Aim:** *This research specifically seeks to address: 1. The physiological processes that occur during the dying process after withdrawal of life supporting therapy (WLST). 2. Whether key markers can be identified that predict time to death following WLST in the potential organ donor. 3. Whether*

[6] Studies looking to remove tissues from DCD donors pre asystole falls under the Mental Capacity Act 2005 and/ or the Mental Capacity Act (Northern Ireland) 2016

				the function of transplanted organs can be predicted from premortem changes identified in the donor. 4. Whether an intervention in the donor can be identified that improves the function of a transplanted organ. **Approvals**: *REC, MCA, HRA, HTA, RINTAG and NHSBT operational written confirmation. Application managed by the ODT Research Facilitation Team.*
7	**Other studies**	O	Proposals which *may* require access to relevant material and/ or donors and is expected to have an impact on the donation, retrieval, and/ or transplantation processes.	**Name**: *Collection and characterization of human olfactory ensheathing cells* **Aim**: *To obtain both olfactory bulbs from adult, brain stem dead patients who undergo organ donation after brain stem death confirmation (DBD)* **Approvals**: *REC, HRA, HTA, RINTAG and ODT SMT. NHSBT operational written confirmation TBC. Application managed by the ODT Research Facilitation Team.*