NHS BLOOD AND TRANSPLANT

RESEARCH, INNOVATION AND NOVEL TECHNOLOGIES ADVISORY GROUP

AVAILABILITY OF ORGANS FOR RESEARCH

SUMMARY

BACKGROUND

1 This paper investigates the pathway of organs that have been retrieved and not transplanted to assess the availability of organs for research. It also identifies the number of such organs that were offered to and received by research studies within the first 7 months of 2020 (1 January to 31 July 2020).

DATA AND METHODS

2 Organs that were retrieved and not transplanted were obtained from the UK Transplant Registry for UK deceased donors between 1 January 2011 and 31 July 2020. Research outcome was split into three categories: No generic research consent, used for research (under generic or specific consent) and organ disposed of with generic research consent.

3 Research organ offering data was also obtained from the ODT Research Team who are copied into research offers (generic consent only). Text message offer data is manually transcribed on to a spreadsheet and combined with EOS data to determine which studies received the organs.

CONCLUSION

4 Overall, the total number of organs retrieved and not transplanted has steadily increased over time. In addition, the proportion of these organs that have consent/authorisation for research has increased to 95% for 2019. However, the impact of the coronavirus pandemic has meant that the number of organs retrieved and not transplanted in 2020 to-date has been lower than usual.

5 Currently in 2020, 156 organs have been used for research to-date, which again is lower than usual due to the coronavirus pandemic.

6 The proportion of discarded organs where generic research consent/authorisation was ascertained is substantially higher than in previous years; 13% in 2015 compared to 46% for the period January to July 2020.

7 During the period January 2020 to 31 July 2020, 254 retrieved but untransplanted organs were offered to researchers through the National Allocation Scheme. 133 of the 254 organs offered for research were accepted by studies on the ODT Research Registry. In addition to these 133 organs used for research, an additional 23 were used but were not offered through the NAS.

8 Utilised research organs were distributed across many studies which suggests that studies that were ranked lower through the allocation scheme were still able to obtain research organs.

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AVAILABILITY OF ORGANS FOR RESEARCH

BACKGROUND

1 This paper investigates the pathway of organs that have been retrieved and not transplanted; these organs have the potential to be available for research purposes. However, such organs cannot be used for research through the National Allocation Scheme (NAS) if there is no suitable generic consent/authorisation. In some cases, these organs can be used for research if there is specific consent/authorisation.

2 In addition, some of these organs are discarded for a wide range of other reasons (e.g. out-of-hours, not suitable for particular trials, logistical reasons). Within this paper we assess the availability of retrieved but untransplanted organs and identify the number of such organs offered to and received by each research study.

DATA AND METHODS

3 Organs that were retrieved and not transplanted were obtained from the UK Transplant Registry for UK deceased donors between 1 January 2011 and 31 July 2020. Research outcome was split into three categories: No generic research consent, used for research (under generic or specific consent) and organ disposed of with generic research consent.

4 Research organ offering data was also obtained from the ODT Research Team who are copied into research offers (generic consent/authorisation only). Text message offer data is manually transcribed on to a spreadsheet and combined with EOS data to determine which studies received the organs. Please note that there may be some organs that were allocated directly to studies without an offer message being sent out, and therefore these cases will not be included in this dataset.

5 Organs that were offered for research in 2020 are presented in terms of which research studies they were offered to and which studies (if any) they went to. Details on each of these research studies which are listed in the **Appendix.** Study rankings are as at August 2020.

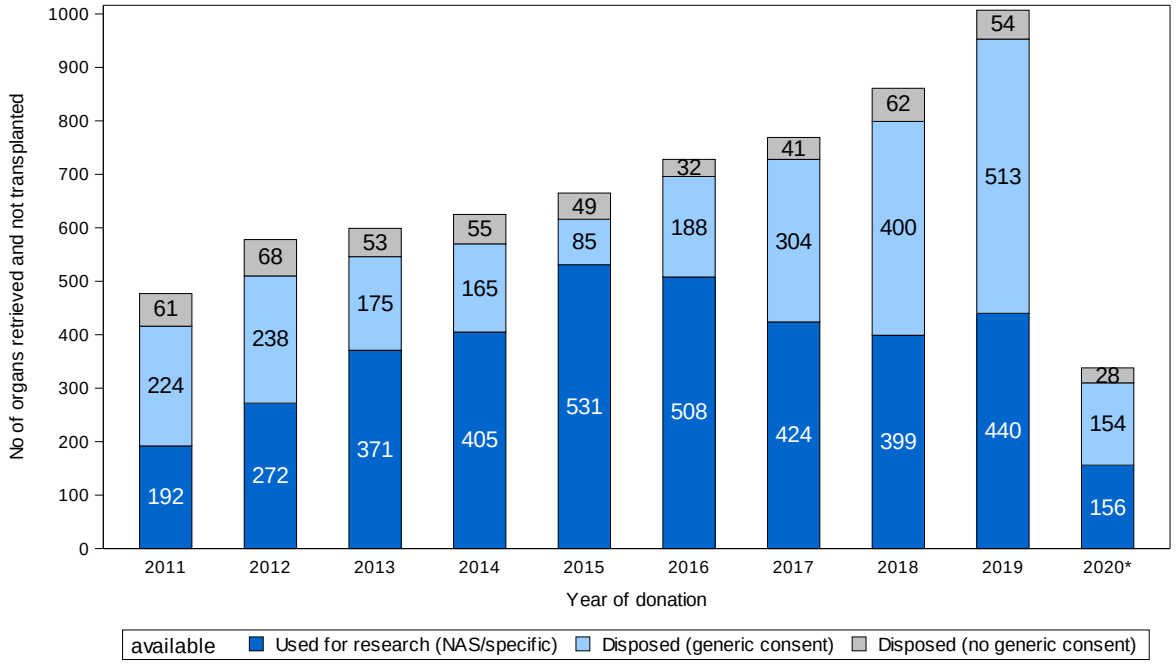
6 Livers isolated for hepatocytes (transplanted or not transplanted) have been excluded from this analysis.

RESULTS

7 **Figure 1** shows the research outcome of UK donor organs that were retrieved and not transplanted between 1 January 2011 and 31 July 2020. Overall, the total number of organs retrieved and not transplanted has steadily increased since 2011. The availability of organs for research was at an all-time high in 2019. However, figures for 2020 are comparably lower due to the coronavirus pandemic. Please note that this paper marks the first time that ODT Research Team data have been merged with UK Transplant Registry data and hence the accuracy of the results (and potentially the proportion of organs used for research) may be higher for 2020 than in previous years.

8 The proportion of potential organs available for research due to being retrieved and not transplanted are shown in **Figure 2,** by research outcome from 1 January 2011 to 31 July 2020. Consent/authorisation for research has been fairly constant in the last five years ranging from 92% to 96% and so the proportion of organs discarded due to a lack of research consent/authorisation is relatively small.

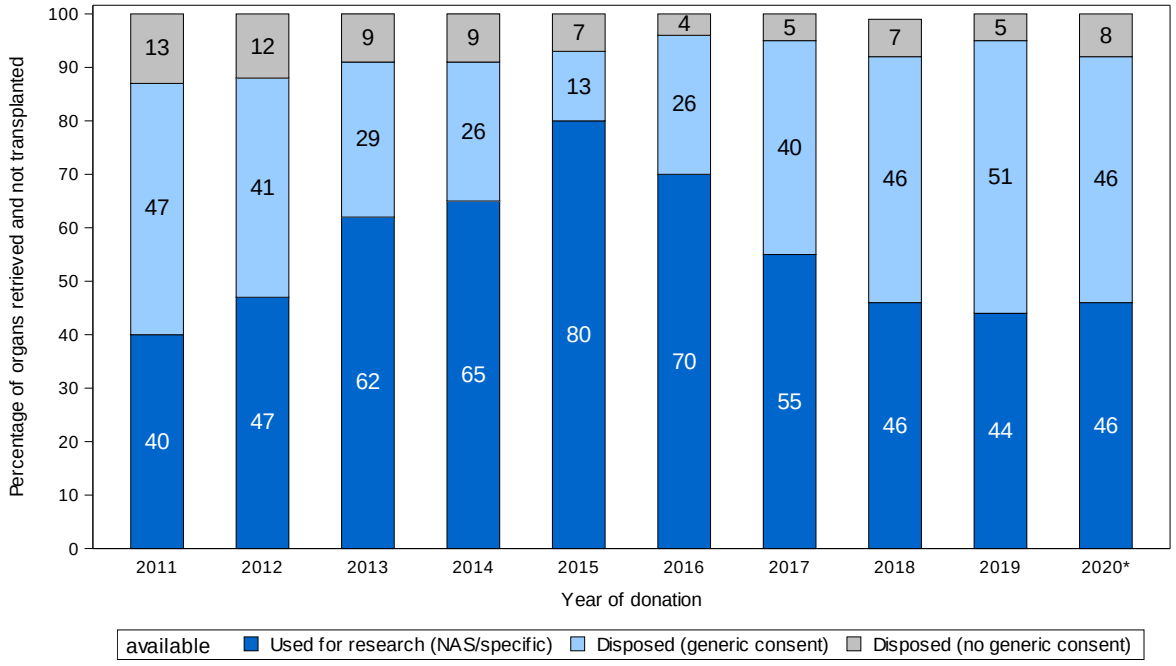
Figure 1 **Number of organs that were retrieved and not transplanted by research outcome, 1 January 2011 - 31 July 2020**



* 1 January to 31 July 2020

Note: On the 20th February 2017 a research prioritisation allocation scheme was introduced

Figure 2 **Percentage of organs that were retrieved but not transplanted by research outcome, 1 January 2011 - 31 July 2020**



* 1 January to 31 July 2020

Note: On the 20th February 2017 a research prioritisation allocation scheme was introduced

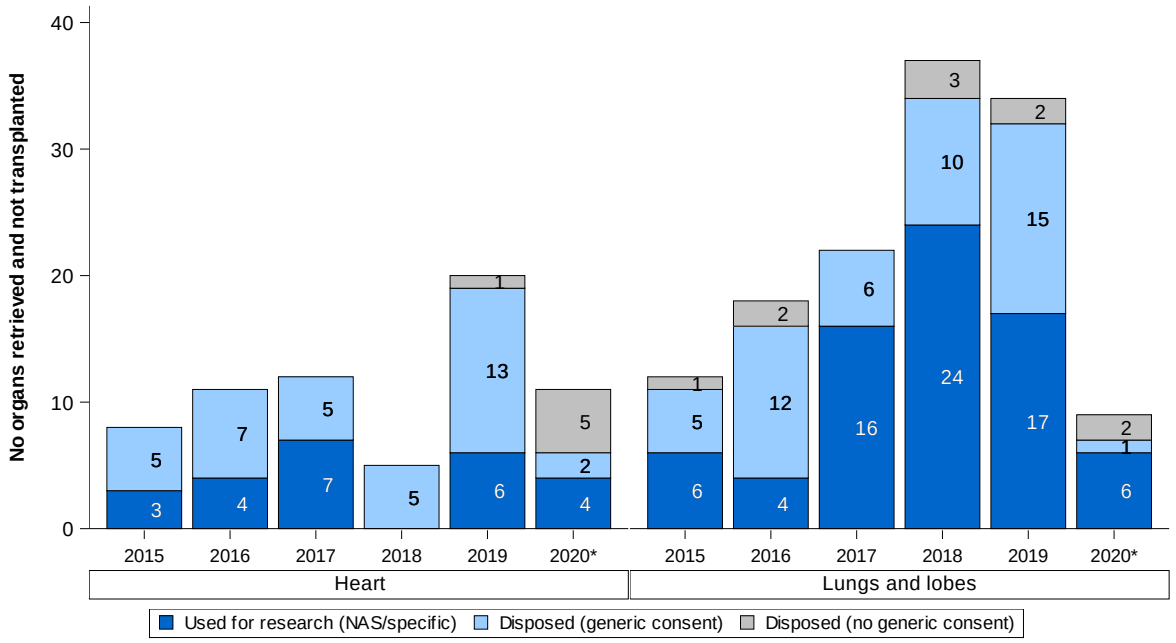
9 In 2015, the number of retrieved but untransplanted organs used for research (under generic or specific consent) was at its highest at 531, after which point the number decreased each year to 399 in 2018 before increasing to 440 in 2019. Currently in 2020, 156 organs have been used for research to-date. However, these figures have been affected by the coronavirus pandemic. Throughout the year all studies continued to receive offers but some have been unable to accept them due to universities, for example, being temporarily closed. Discard rates for organs with generic research consent/authorisation have remained fairly high in recent years, at 46% for the 2020 calendar year to-date.

10 The same information from **Figure 1** (number of organs retrieved and not transplanted) is broken down by organ and illustrated in terms of cardiothoracic organs in **Figure 3** and abdominal organs in **Figure 4**.

11 The number of cardiothoracic organs available for research is small, as seen in **Figure 3.** To-date, four hearts and six lungs have been used for research in 2020.

12 **Figure 4** shows that until 2020, the number of abdominal organs available for research has generally been increasing, particularly for kidneys and livers. . Numbers are lower for 2020 thus far due to reduced donors and suspension of research studies as a result of the coronavirus pandemic.

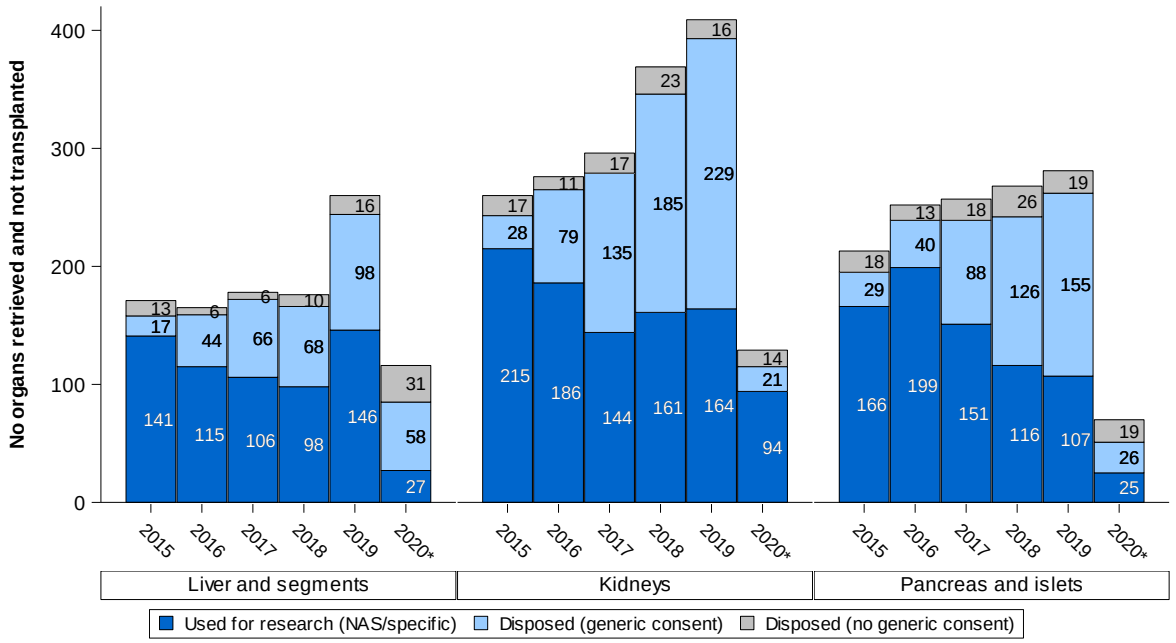
Figure 3 **Number of cardiothoracic organs that were retrieved but not transplanted by research outcome and organ from 2015 to 2020**



* 1 January to 31 July 2020

Note: On the 20th February 2017 a research prioritisation allocation scheme was introduced

Figure 4 **Number of abdominal organs that were retrieved and not transplanted by research outcome and organ from 2015 to 2020**



* 1 January to 31 July 2020

Note: On the 20th February 2017 a research prioritisation allocation scheme was introduced

13 **Table 1** shows the total number of retrieved but untransplanted organs that were offered and accepted by organ type from 1 January 2020 to 31 July 2020. 254 organs from 191 deceased organ donors were offered to researchers through the National Allocation Scheme (NAS) during this time. 133 of the 254 organs offered for research were accepted by studies on the ODT Research Registry. 115 organs were disposed of and of the 6 remaining organs:

- 2 livers were returned to the donors' bodies
- 2 kidneys were transplanted when the recipient centre changed their mind
- 1 liver was transplanted when the recipient centre changed their mind
- 1 heart was used for valves (which should have occurred before being offered for research

14 In addition to these 133 organs used for research, an additional 23 were not offered through the NAS but were used for research (hence used under specific consent/authorisation). This brings the total to 156 organs that were used for research during 1 January 2020 to 31 July 2020.

15 65% of organs were offered outside of core hours or over weekends and bank holidays.

16 62% of organs offered during core hours were accepted, 45% offered outside of core hours were accepted and 42% of organs offered over weekends and bank holidays were accepted.

Table 1 Organs offered and accepted for research through the National Allocation Scheme (NAS) 1 January 2020 to 31 July 2020

	Organs offered	Organs accepted	
Organ type	**N**	**N**	**% of offered**
Heart	6	3	50
Lungs	5	4	80
Liver	85	21	25
Kidney	119	93	78
Pancreas	39	12	31
TOTAL (offered through NAS)	**254**	**133**	**52**
TOTAL (not offered through NAS)	**254**	**23**	**-**
TOTAL		**156**	**-**

17 **Table 2** and **3** show the total number of retrieved but untransplanted organs offered to and received by research studies from 1 January 2020 to 31 July 2020 (including those received outside of the NAS), for each of cardiothoracic and abdominal organs, respectively. The tables show that the research organs utilised were distributed across many studies as such lower ranked studies were still able to obtain research organs overall.

Table 2 Cardiothoracic organs received by study from 1 January 2020 to 31 July 2020

Organ	Study Number	Location	Ranking as at August 2020	Organs offered through NAS	Organs received through NAS		Organs received outside NAS	Total organs received	
				N	N	% of offered	N	N	%
Hearts	83[1]	Newcastle	1	6	-		1	1	33
	67	Imperial	2	6	2	33	-	2	67
	Unknown	NA	NA	6	1	16	-	1	16
	Total		**88**		**3**		**1**	**4**	**100**
Lungs	58	Edinburgh	NA[2]	5	2	40	-	2	33
	66	Newcastle	NA[2]	5	2	40	1	3	50
	Unknown	NA	NA				1	1	17
	Total				**4**		**2**	**6**	**100**
Total cardiothoracic organs					**7**		**3**	**10**	**100**

NOTES
[1] Study 83 is unable to accept hearts that have already been on the Organ Care System (OCS)
[2] As of the May 2019 RINTAG` meeting, the lung studies have agreed to allocate the lungs between themselves

Table 3 Abdominal organs received by study from 1 January 2020 to 31 July 2020

Organ	Study Number	Location	Ranking as at August 2020	Organs offered through NAS	Organs received through NAS		Organs received outside NAS	Total organs received	
				N	N	% of offered	N	N	%
Liver and segments	21	Addenbrookes	1	85	1	1	2	3	11
	52	Newcastle	2	85	1	1	0	1	4
	35	Birmingham	3	85	9	11	0	9	33
	56	Edinburgh	6	85	2	2	0	2	7
	33	Birmingham	7	85	3	4	2	5	19
	84	Birmingham	7	85	4	5	1	5	19
	Unknown	NA	NA	85	1	1	1	2	7
	Total				**21**		**6**	**27**	**100**
Kidney	2	Addenbrookes	2	119	37	31	1	38	40
	23	Addenbrookes	3	119	23	19	0	23	24
	73	Guy's	3	119	4	3	0	4	4
	63	Guy's	4	119	2	2	0	2	2
	40	Royal Free	6	119	3	3	0	3	3
	96[1]	Newcastle	7	62[1]	2	3	0	2	2
	31	Cardiff	Tissue bank	119	18	15	0	18	19
	36	Coventry	Tissue bank	119	4	3	0	4	4
	Total				**93**		**1**	**94**	**100**

NOTES
[1] study 96 went live on 1 March 2020

Table 3 Abdominal organs received by study from 1 January 2020 to 31 July 2020 (ctd)

Organ	Study Number	Location	Ranking as at August 2020	Organs offered through NAS	Organs received through NAS		Organs received outside NAS	Total organs received	
				N	N	% of offered	N	N	%
Pancreas and islets	3	Addenbrookes	1	39	7	18	0	7	28
	20	Newcastle	1	39	1	3	6	7	28
	85	Edinburgh	2	39	3	8	0	3	12
	82	Oxford	3	39	1	3	0	1	4
	45	Oxford	-	39		0	2	2	8
	47	King's	-	39		0	2	2	8
	Unknown	NA	NA				3	3	12
	Total				**12**		**13**	**25**	**100**
Total abdominal organs					**126**		**20**	**146**	**100**

CONCLUSION

18 Overall, the total number of organs retrieved and not transplanted has steadily increased over time. In addition, the proportion of these organs that have consent/authorisation for research has increased to 95% for 2019. However, the impact of the coronavirus pandemic has meant that the number of organs retrieved and not transplanted in 2020 to-date has been lower than usual.

19 Since 2015, the number of retrieved but untransplanted organs used for research has been decreasing each year to 399 in 2018 before an increase to 440 in 2019. Currently in 2020, 156 organs have been used for research to-date, which again is lower than usual due to the coronavirus pandemic. Throughout the year all studies continued to receive offers but some have been unable to accept them due to universities, for example, being temporarily closed.

20 The proportion of discarded organs where generic research consent/authorisation was ascertained is substantially higher than in previous years; 13% in 2015 compared to 46% for the period January to July 2020.

21 During the period January 2020 to 31 July 2020, 254 retrieved but untransplanted organs were offered to researchers through the National Allocation Scheme. 133 of the 254 organs offered for research were accepted by studies on the ODT Research Registry. 65% of organs were offered outside of core hours or over weekends and bank holidays. 62% of organs offered during core hours were accepted, 45% offered outside of core hours were accepted and 42% of organs offered over weekends and bank holidays were accepted.

22 In addition to these 133 organs used for research, an additional 23 were used but were not offered through the NAS.

23 Utilised research organs were distributed across many studies which suggests that studies that were ranked lower through the allocation scheme were still able to obtain research organs.

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APPENDIX – Research studies ranking as at August 2020

Organ	Study	Rank	Start date	End date	Location	Study Title
Heart	83	1	2019	2022	Newcastle	Evaluation of Hypothermic Oxygenated Perfusion (HOP) Ex-Vivo Heart Perfusion to Expand the Donor Pool and Improve Transplant Outcomes
Heart	67	2	2017	2021	Imperial	Structural and functional analysis of intact myocardium and isolated cells from explanted hearts
Lungs	58	1	2017	2020	Edinburgh	Multiplexed Optical Molecular Imaging and Sensing during Ex Vivo Lung Perfusion (EVLP)
Lungs	66	1	2017	2020	Newcastle	Further Evaluation of Ex Vivo Lung Perfusion to Improve Transplantation Outcomes
Liver	21	1	2014	2020	Addenbrookes	Development of pre-transplant normothermic perfusion reconditioning for human livers donated after circulatory death
Liver	52	2	2015	2020	Newcastle	Establishing ex-vivo normothermic and hypothermic perfusion of livers for transplantation
Liver	35	3	2014	2024	Birmingham	Normothermic Liver Perfusion
Liver	56	6	2016	2022	Edinburgh	Human Hepatic Progenitor Cells as a Source of Liver Regeneration
Liver	33	7	2013	2020	Birmingham	Expression and Function of Immune Regulatory Proteins in Human Liver
Liver	84	7	2019	2023	Birmingham	Investigating how inflammation determines the development and outcome of inflammatory liver diseases, and whether new targets for drug therapies can be identified
Kidney	2	2	2012	2021	Addenbrookes	Study of renal ischaemia-reperfusion injury and its amelioration. Note: This study has now been split into separate parts to allow the team to accept organs with restrictions
Kidney	23	3	2012	2022	Addenbrookes	Characterisation of ischaemia reperfusion injury in human kidneys
Kidney	73	3	2018	2021	Guy's	Mobilisation and depletion of passenger leukocytes during warm perfusion of discarded deceased donor kidneys
Kidney	63	4	2016	2020	Guy's	Transplanting the untransplantable - extending antibody incompatible transplantation using a normothermic perfusion model with cytoprotective agents
Kidney	40	6	2014	2024	Royal Free	Identification of genes involved in renal, electrolyte and urinary tract disorders
Kidney	96	7	2020	2024	Newcastle	Development of a human precision cut slice (PCS) model to study renal inflammation and fibrosis
Kidney	31	80	-	-	Cardiff	Donate for Research Initiative
Kidney	36	80	-	-	Coventry	Arden Tissue Bank

APPENDIX – Research studies ranking as at August 2020

Organ	Study	Rank	Start date	End date	Location	Study Title
Pancreas	3	1	2012	2021	Addenbrookes	Study of Pancreas Function, Physiology, Pathology and Therapeutics. Note: This study has now been split into separate parts to allow the team to accept organs with restrictions
Pancreas	20	1	2005	2020	Newcastle	Process development for islet isolation targeted at enhancing islet yield and viability.
Pancreas	85	2	2014	2022	Edinburgh	Use of deceased donor pancreata to optimise and improve the clinical islet isolation process in a research environment
Pancreas	82	3	2019	2022	Oxford	Development of an ex-vivo endocrine pancreas for the investigation and treatment of diabetes
Pancreas	45	70	2009	2021	Oxford	Studies of Factors Influencing the Structure and Function of Human Pancreatic Islets for Transplantation
Pancreas	47	70	2002	2025	King's	King's Islet lab