

By email to: [REDACTED]

Human Tissue Authority

2nd Floor
2 Redman Place
London
E20 1JQ

Tel 020 7269 1900

Web www.hta.gov.uk

Email enquiries@hta.gov.uk

Date: 21 February 2022

Dear [REDACTED]

Freedom of Information request

Thank you for your request for information under the Freedom of Information Act (FOIA), which was received by the Human Tissue Authority (HTA) on 20 January 2022. Your email outlined the following request:

[REDACTED]

I am writing to request a copy of the HTA Decision-Making Framework and the HTA Standard Operating Procedures. According to HTA Code of Practice F part 1 (para 106) these documents are available upon request. I assume that the HTA Decision-Making Framework is the HTA policy for the assessment of living organ donation cases, although the wording in the Code of Practice was ambiguous. If there are any further documents pertaining to the assessment of living organ donors, I would be grateful if you could send me these. I am looking at more detailed information on these assessments than is available from the online guidance documents for professionals.

I would also like to request any documents on training and enhanced training of Independent Assessors, for the purposes of interviews with the prospective organ donor, child or adult.

[REDACTED]

Clarification

We wrote to you via email on 26 January 2022 requesting the following clarification:

“Further to your request, to ensure we provide you with the necessary information, could you please confirm under which legislation you will be reviewing the HTA’s role in assessing living organ donation?”

As you may be aware, [The Human Tissue Act 2004](#) (the Act) sets out the legal framework for the removal, storage and use of human organs and tissue from living and deceased donors. The Act covers England, Wales, and Northern Ireland, there is separate legislation for Scotland, [Human Tissue Act \(Scotland\) Act 2006](#).

Both these legislations are different, and therefore there are differences in the way the cases are assessed and also the role of the court.”

You responded on 26 January 2022 with the following clarification:

“The following should clarify what documents I am seeking:

In relation to children, living donation is prohibited from under 16 year olds in Scotland so I am seeking the HTA Decision-Making Framework and the HTA Standard Operating Procedures applicable to England and Wales. HTA Code of Practice F part 1 (106), which applies to England and Wales only, refers to a “HTA Decision-Making Framework” and “HTA Standard Operating Procedures”. I assume that these cover both adults and children but if they do not please could you send me the documents for both as [REDACTED]

[REDACTED] Also, just to be clear, if there are additional documents concerning adults without capacity to consent, I would need these too as [REDACTED]

[REDACTED] All HTA documents seem to also cover adults with incapacity so I don’t think this will be an issue but in the interests of efficiency I thought I would clarify this.

In relation to Scotland, I have read the 2017 Human Tissue Authority guidance for transplant teams, Independent Assessors and Accredited Assessors in Scotland, available online. There is no reference to any equivalent decision-making framework/operating procedures for Scotland for the assessment of living adult donation. If any additional guidance exists could you please send me this too.

Finally, is there any record available of the numbers of applications for HTA approval of living donation that are refused, ideally broken down by applicant age in England and Wales so I can separate children from adults? If such data for the past 5 years are available I would be very grateful for this information.”

Response

[The Human Tissue Act 2004](#) and [The Human Tissue Act 2004 \(Persons who Lack Capacity to Consent and Transplants\) Regulations 2006](#) (also referred to as ‘the Regulations’) place an obligation on the HTA to assess all referrals for living organ donation. HTA Code of Practice F part 1 applies to England, Wales and Northern Ireland rather than just England and Wales.

In response to your request, please find attached the following documents as an appendix to this letter which, where applicable, cover Scotland as well as England, Wales and Northern Ireland:

- Presentations used to deliver training to new Independent Assessors;
- A copy of the agenda for the most recent training day for new Independent Assessors held in October 2021 (please note, as part of the training day there is also a presentation from a Living Donor Coordinator and from experienced IAs. These presentations have not been included as they are external to the HTA);
- HTA-GD-009 External guidance for Transplant Teams and Independent Assessors;
- HTA-GD-021 External guidance for transplant teams and IAs and AAs in Scotland;
- HTA-GD-027 External guidance for living organ donors on the HTA's independent assessment process;
- HTA-POL-102 Internal Policy for the assessment of living organ donation cases;
- HTA-SOP-110 Independent Assessor Reaccreditation Process;
- HTA-SOP-111 Assessment process for living donor transplant cases;
- HTA-SOP-114 Internal Living Organ Donation Regulatory Decision Making;
- HTA-SOP-115 Internal Reconsideration of HTA living organ donation decision under Regulation 13 and;
- HTA POL-037 HTA Decision-Making Framework.

You also requested any record available of the numbers of applications for HTA approval of living donation that are refused, broken down by applicant age in England and Wales for the past five years.

In the period 1 January 2017 to 31 December 2021, the HTA did not refuse any living organ donation applications. The HTA has never received an application for a child to be a living solid organ donor.

Section 40 FOIA

In reviewing the information you have requested, we have noted that some of information contained within the documents is exempt by virtue of the fact that it is personal data of third parties, disclosure of which would be unfair to the individuals concerned and would constitute unlawful processing of their personal data.

Section 40(3A)(a) FOIA states that information is absolutely exempt from disclosure if its disclosure would breach any of the any of the principles relating to the processing of personal data (“the DP principles”), as set out in Article 5 of the General Data Protection Regulation (“GDPR”). Insofar as the Report contains information relating to identifiable individuals the HTA has concluded that disclosure under FOIA would breach the first DP principle.

Parts of the documents have been redacted so that it does not include:

- personal information which identifies an individual directly;

As stated above, this information is exempt under Section 40(2), which is an absolute exemption which does not require the HTA to consider the public interest test.

Further information

If you are unhappy with the way the HTA has handled your request for information in this case, you may in the first instance ask us for an internal review by writing to us at the above postal or email address.

If you remain dissatisfied with the handling of your request, you have the right to appeal directly to the Information Commissioner for a decision, at the address below. There is no charge for making an appeal.

Information Commissioner's Office
Wycliffe House
Water Lane
Wilmslow
Cheshire SK9 5AF

Telephone: 08456 30 60 60 or 01625 54 57 45

Website: www.ico.org.uk

Yours sincerely

