

Directions given under the Human Tissue Act 2004, the Human Tissue (Quality and Safety for Human Application) Regulations 2007 (As amended) (SI 2007 No.1523) and the Quality and Safety of Organs Intended for Transplantation Regulations 2012 (SI 2012 No.1501)

Directions on licence fee structure for the financial year 2019/20

Ref 001/2020

These Directions are

Statutory Directions

Section of the Human Tissue Act 2004, the Human Tissue (Quality and Safety for Human Application) Regulations 2007 (SI 2007 No.1523) and the Quality and Safety of Organs Intended for Transplantation Regulations 2012 (SI 2012 No.1501) providing for these Directions	Schedule 3, paragraph 2(4)(f) of the Human Tissue Act 2004, Regulation 8 of the Human Tissue (Quality and Safety for Human Application) Regulations 2007 and Regulation 6 of the Quality and Safety of Organs Intended for Transplantation Regulations 2012
These Directions come into force on	1 April 2020
These Directions remain in force	Until revoked

1. These Directions revoke Directions 001/2019.
2. These Directions are made by the Human Tissue Authority under Schedule 3, paragraph 2(4)(f) of the Human Tissue Act 2004 and as applied by Regulation 8 of the Human Tissue (Quality and Safety for Human Application) Regulations 2007 (as amended) and Regulation 6 of the Quality and Safety of Organs Intended for Transplantation Regulations 2012.
3. These Directions set out the licence fee structure of the Human Tissue Authority for the financial year commencing 1 April 2020.
4. Schedule 3, paragraph 2(4)(f) of the Human Tissue Act 2004, and as applied by Regulation 8 of the Human Tissue (Quality and Safety for Human Application) Regulations 2007 (as amended) (SI 2007 No. 1523) and Regulation 6 of the Quality and Safety of Organs Intended for Transplantation Regulations 2012 (SI 2012 No.1501), provides that "it shall be a condition of a licence...that there shall be paid to the Authority at such times as may be specified in directions sums of such amount as may be so specified in respect of its costs in connection with superintending compliance with the terms of licences."
5. The Human Tissue Authority licence fee structure:

Sectors (type of licence)	Post mortem sector (PM)	Research sector	Public display sector	Anatomy sector	Human application sector	Organ donation and transplant	Licence for Removal
Main Licence fee:	£3,420	£3,530	£1,315	£2,550	£5,720	£4,225	£835
PM activities:							
• Making of a PM	£2,405	-	-	-	-	-	-
• Storage	£345	-	-	-	-	-	-
• Removal	£345	-	-	-	-	-	-
HA activities:							
• 5 or more tissue types	-	-	-	-	£1,070	-	-
• Processing	-	-	-	-	£3,045	-	-
• Procurement	-	-	-	-	£1,070	-	-
• Testing	-	-	-	-	£1,070	-	-
• Storage	-	-	-	-	£1,070	-	-
• Distribution	-	-	-	-	£540	-	-
• Import	-	-	-	-	£540	-	-
• Export	-	-	-	-	£540	-	-
ODT - two or fewer organs	-	-	-	-	-	£3,155	-
ODT - three organs	-	-	-	-	-	£6,295	-
ODT - four organs	-	-	-	-	-	£8,385	-
ODT - five or more organs	-	-	-	-	-	£10,400	-
Organisation responsible for procuring organs from deceased donors	-	-	-	-	-	£30,215	-
Satellite licence fees: (First 4 satellites)	£1,550	£835	£325	£410	£3,640	-	-
Satellite licence fees: (Each satellite over 4)	£805	£420	£165	£205	£2,030	-	-
Satellite activity fees:							
• Making of a PM	£2,405	-	-	-	-	-	-
Application fees:							
Main licence	£3,225	£3,225	£3,225	£3,225	£4,160	£3,225	-
Satellite	£825	£825	£825	£825	£885	-	-
Temporary Licence fees: *							
Six months licence	£4,080	£4,110	£3,555	£3,865	£5,590	-	-

* For temporary licences the fee payable replaces the usual application fee and annual fees and the licence period is for six months from the date the licence is granted. The licence will cease to be valid after this period and all licence revocation documentation must be completed and returned to HTA. Any activities required on a temporary licence will be charged at 50% for a six month licence.

Date 31 March 2020



Signed.....

Allan Marriott-Smith
Chief Executive
Human Tissue Authority