

# Termination of licensable activities – Closure Pro Forma for commercial establishments licensed in the Human Application sector

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**Please note: This form is for commercial establishments that are not private hospitals – if your establishment is part of the NHS or a private hospital please complete the form for NHS establishments and private hospitals.**

## Guidance

This form is for establishments licensed by the HTA under the Human Tissue (Quality and Safety for Human Application) Regulations 2007 (as amended) (the Q&S Regulations).

To be completed by the Licence Holder or Designated Individual **if**:

- a) The licensed establishment is planning to close or terminate its activities, or if the licence is being revoked;
- b) If the closure is related to a satellite (section A only);
- c) A third party carrying out licensable activities on behalf of the licensed establishment is planning to close or terminate its activities.

This form has been devised to meet the requirements set out in paragraph 267 to 270 of HTA Guide to Quality and Safety Assurance for Human Tissues and Cells for Patient Treatment (the Guide) as implemented by HTA Directions 001/2021.

**Section A: Licensed establishment details**

1. (a)	Name and address of the establishment that is closing, or where termination of activities is taking place	Name: Address:
1. (b)	Establishment licence number	
1. (c)	What does the termination/closure relate to?	<input type="checkbox"/> The licensed establishment <input type="checkbox"/> A third party <input type="checkbox"/> A satellite site (if this relates to a satellite site you only need to complete Section A of the form)
2. (a)	Name of the current Designated Individual (DI) at the licensed establishment	
2. (b)	Names of the former DI	
3. (a)	Is relevant material to be transferred to a licensed establishment?	<input type="checkbox"/> Yes if yes, please state date of transfer: To: <input type="checkbox"/> A third party licensed for storage <input type="checkbox"/> A satellite site licensed for storage <input type="checkbox"/> No (please detail below the reasons no transfer is taking place)
3. (b)	Name, address and licence number of the licensed establishment to which stored tissues/cells and documentation are being transferred	Establishment name: Address: Licence number:
3. (c)	Please provide the name of a contact person who will deal with all queries from the HTA and the receiving establishment following the termination/closure	Name: Postal address: Email address: Telephone number:

4.	Licensable activity(ies) taking place (tick all which are relevant)	
	Under the Human Tissue Act 2004	<input type="checkbox"/> Section 16(2)(e)(i) and (ii) – The storage of the body of a deceased person or relevant material which has come from a human body for use for a Scheduled Purpose, other than transplantation
	Under the Human Tissue (Quality and Safety for Human Application) Regulations 2007	<input type="checkbox"/> Procurement <input type="checkbox"/> Testing <input type="checkbox"/> Processing <input type="checkbox"/> Storage <input type="checkbox"/> Distribution <input type="checkbox"/> Import <input type="checkbox"/> Export
5. (a)	Date of expected termination of activities	
5. (b)	Date of expected establishment closure	
6.	Paragraph 268(g) of the Guide requires that an establishment which is closing or terminating activities must carry out an audit of stored relevant material <u>prior</u> to the transfer of any stored tissues or cells.  <b>Only complete the following parts of this section if transfer of tissues and cells is to take place</b>  Please confirm the following:	
6. (a)	The audit has been completed	<input type="checkbox"/> Yes <input type="checkbox"/> No
6. (b)	A copy of the report is attached to this form	<input type="checkbox"/> Yes <input type="checkbox"/> No
6. (c)	A copy of the report has been provided to the receiving establishment	<input type="checkbox"/> Yes <input type="checkbox"/> No
6. (d)	Where material will continue to be stored and/or used, it has been ensured that this is in line with the original consent given	<input type="checkbox"/> Yes <input type="checkbox"/> No
6. (e)	Were any discrepancies or anomalies found following the audit?	<input type="checkbox"/> Yes <input type="checkbox"/> No (If no, proceed to question 7)
	If yes, please provide details below, using additional sheets where necessary:	

6. (f)	Have all discrepancies and anomalies been resolved?	<input type="checkbox"/> Yes <input type="checkbox"/> No  <b>If no, please note that all discrepancies and anomalies should be resolved prior to establishment closure/termination of licensable activity(ies).</b>
7.	What steps have been taken to ensure that the transport of tissues and/or cells is carried out under conditions that maintain the integrity and quality of tissues and/or cells?	

## Section B: Termination agreement

Paragraph 268 of the Guide lists requirements for termination agreements relating to the termination of licensed activities (this includes closure of an establishment or third party establishment). Please give details about the provision in your termination agreement.

8.	Is a termination agreement in place?  (If it is not, please note that termination agreements are a requirement under the Q&S Regulations and the Guide and you should contact the HTA for advice)	<input type="checkbox"/> Yes <input type="checkbox"/> No
9.	Please confirm that the termination agreement in place includes the following:	
9. (a)	Procedures for transfer of tissues and/or cells and records	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
9. (b)	Provision to secure that all records, including raw data, which are critical to the safety and quality of tissues or cells shall be kept so as to ensure access to this data for at least 10 years after expiry date, clinical use or disposal	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
9. (c)	Provision to secure that any patient records are retained for 30 years.	<input type="checkbox"/> Yes <input type="checkbox"/> No
9. (d)	An acknowledgement of the accepting DI and/or third party.	<input type="checkbox"/> Yes <input type="checkbox"/> No
9. (e)	An obligation by the accepting DI and/or third party to retain documentation and records required to be kept under the Q&S Regulations, the Directions and documentation and records referred to in Section D.	<input type="checkbox"/> Yes <input type="checkbox"/> No
9. (f)	An obligation to ensure that tissues and/or cells are transferred (subject to the consent of the donor) without delay to another licensed establishment following termination of activities.	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
9. (g)	Provision to secure compliance with the traceability and coding provisions of the Q&S Regulations and Directions.	<input type="checkbox"/> Yes <input type="checkbox"/> No

9. (h)	Provision for the transfer of minimum information and coding information for retention to another licensed establishment including the information referred to in Section D.	<input type="checkbox"/> Yes <input type="checkbox"/> No
9. (i)	Provision in relation to the transfer of the registers kept in accordance with the HTA Directions to another licensed establishment, or alternatively to the HTA.	<input type="checkbox"/> Yes <input type="checkbox"/> No
9. (j)	Provision in relation to the transfer of any records or information retained in accordance the register and recording obligations set out in the Guide to another licensed establishment or alternatively transfer to the HTA.	<input type="checkbox"/> Yes <input type="checkbox"/> No
9. (k)	Provision for the transfer of any third party agreement to another licensed establishment or alternatively transfer to the HTA.	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
9. (l)	Provision to secure compliance with the duty of the DI and/or third party regarding the disclosure of information and confidentiality.	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
9. (m)	Prior to the transfer of any tissues/cells an audit of stored tissue and/or cells will be carried out and any discrepancies or anomalies will be resolved. A copy of the audit report will be sent to both the HTA and the receiving establishment.	<input type="checkbox"/> Yes <input type="checkbox"/> No
9. (n)	The transfer of tissues and/or cells will be carried out under conditions that ensure that the integrity and quality of tissues and/or cells is maintained.	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
	<b>Please provide details of how this will be ensured:</b>	

**Please note: If you have ticked “No” to any questions in Section B please amend the termination agreement to include the provision. If this is not feasible contact a member of the Regulation Team at the HTA for approval.**

## Section C: Termination of third party activities

This section should be completed by licensed establishments who have agreements with third parties who are carrying out licensable activities on their behalf, and the third parties who are terminating licensable activities.

10.	Please confirm that all staff working under the third party agreement have been reminded that statutory confidentiality requirements continue to apply following the termination of the third party agreement (s13 Q&S Regulations and paragraphs 18 and 19 of the Guide) .  (This should be a provision of the third party agreement)	<input type="checkbox"/> Yes <input type="checkbox"/> No
<b>Please provide details of how this statutory requirement has been met:</b>		
11.	Where the third party processes on behalf a licensed establishment please confirm that the third party agreement includes provision for the transfer of tissues and/or cells to another licensed establishment in the event of closure/termination.	<input type="checkbox"/> Yes <input type="checkbox"/> No
12.	Please confirm that all third parties have ensured that registers, documentation, records and information retained pursuant to the HTA Directions have been transferred to another licensed establishment.	<input type="checkbox"/> Yes <input type="checkbox"/> No
13.	Please confirm that all third parties have ensured that tissues and/or cells are transferred (subject to the consent of the donor) to a licensed establishment	<input type="checkbox"/> Yes <input type="checkbox"/> No

## Section D: Information and/or documentation to be retained on licensed premises

Please confirm that the following documentation will be transferred to another licensed establishment and retained for a minimum of 30 years (paragraphs 177 and 178 of the Guide and paragraph 210 in relation to serious adverse events and reaction).

Records/documentation	Please tick
<p><b>Registers</b></p> <p>i. A register of the types and quantities of tissues and/or cells, procured, tested, preserved, processed, stored and distributed or otherwise disposed of, and on the origin and destination of tissues and cells intended for human applications.</p> <p>ii. A register of the coded data assigned to each donor and donation of tissues and cells.</p>	<p><input type="checkbox"/> Yes</p> <p><input type="checkbox"/> No</p> <p><input type="checkbox"/> Yes</p> <p><input type="checkbox"/> No</p>
<p><b>Donor and donation identification (177a)</b></p> <p>That will include at least:</p> <p>i. Identification of the procurement organisation or establishment.</p> <p>ii. Unique donation identification number.</p> <p>iii. Date of procurement.</p> <p>iv. Place of procurement.</p> <p>v. Type of donation (for example single or multi tissue, autologous or allogeneic, living or deceased).</p>	<p><input type="checkbox"/> Yes</p> <p><input type="checkbox"/> No</p>
<p><b>Product identification (177b)</b></p> <p>That will include at least:</p> <p>i. Identification of the tissue establishment.</p> <p>ii. Type of tissue and / or cell / product (basic nomenclature).</p> <p>iii. Pool number (if applicable).</p> <p>iv. Split number (if applicable).</p> <p>v. Expiry date.</p> <p>vi. Tissue and / or cell status (i.e. quarantined, suitable for use etc).</p> <p>vii. Description and origin of the product or products, processing steps, materials and additives coming into contact with the tissues and/or cells and having an effect on their quality and/or safety.</p> <p>viii. Identification of the facility/establishment issuing the final label.</p>	<p><input type="checkbox"/> Yes</p> <p><input type="checkbox"/> No</p>
<p><b>Human application identification (177c)</b></p> <p>That will include at least:</p> <p>i. Date of distribution and/or disposal.</p> <p>ii. Identification of the clinician or end user /facility /establishment.</p>	<p><input type="checkbox"/> Yes</p> <p><input type="checkbox"/> No</p>



<p><b>Where end use information is kept by the closing or terminating establishment:</b></p> <p>i. Identification of the recipient. ii. Date of application.</p>	<p><input type="checkbox"/> Yes <input type="checkbox"/> No</p>
<p><b>Serious adverse events and reactions:</b></p> <p>a. all records associated with serious adverse events or reactions</p> <p>b. any notifications by the DI of all relevant information about suspected serious adverse events or serious adverse reactions notified to it by procurement organisations, organisations responsible for human application or third parties</p> <p>g. the SOP for the identification, investigation, reporting, recording and notification of serious adverse events and reactions</p> <p>h. the information provided to end users and other organisations responsible for human application about how to report serious adverse events and reactions.</p>	<p><input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> No</p>

Please return this form by email to [licensing@hta.gov.uk](mailto:licensing@hta.gov.uk).