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

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

**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**:

1. The licensed establishment is planning to close or terminate its activities, or if the licence is being revoked;
2. If the closure is related to a satellite (section A only);
3. 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**

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| 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? | [ ]  The licensed establishment[ ]  A third party[ ]  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? | [ ]  Yes (if yes, please state date of transfer: )To:[ ]  A third party licensed for storage[ ]  A satellite site licensed for storage[ ]  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 at 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 | [ ]  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 | [ ]  Procurement [ ]  Testing[ ]  Processing [ ]  Storage[ ]  Distribution[ ]  Import[ ]  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 relevant material prior to the transfer of any stored tissues or cells, where such transfer is to take place.**Only complete the following parts of this section if transfer of tissues and cells is to take place**Please confirm the following:  |
| 6. (a) | The audit has been completed | [ ]  Yes [ ]  No |
| 6. (b) | A copy of the report is attached to this form | [ ]  Yes [ ]  No |
| 6. (c) | A copy of the report has been provided to the receiving establishment | [ ]  Yes [ ]  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 | [ ]  Yes [ ]  No |
| 6. (e) | Were there any discrepancies or anomalies found following the audit?  | [ ]  Yes [ ]  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?  | [ ]  Yes [ ]  NoIf no, please note that all discrepancies and anomalies should be resolved prior to establishment closure/termination of licensable activity(ies). |
| 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.

**Note: The HTA’s preference is that records relating to traceability and raw data, where not transferred to an establishment along with tissues and cells, remain on site wherever possible, preferably under the control of a DI of any other Human Application licence within the hospital or organisation.**

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| 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 except where records are remaining on site) | [ ]  Yes (If yes, proceed to question 9) [ ]  No (if no, proceed to question 10) |
| 9. | Please confirm that the termination agreement in place includes the following: |
| 9. (a) | Procedures for transfer of tissues and/or cells and records | [ ]  Yes [ ]  No [ ]  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. | [ ]  Yes [ ]  No [ ]  N/A |
| 9. (c) | Provision to secure that any traceability records are retained for 30 years. | [ ]  Yes [ ]  No  |
| 9. (d) | An acknowledgement of the accepting DI and/or third party. | [ ]  Yes [ ]  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. | [ ]  Yes [ ]  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. | [ ]  Yes [ ]  No [ ]  N/A |
| 9. (g) | Provision to secure compliance with the traceability and coding provisions of the Regulations and Directions. | [ ]  Yes [ ]  No  |
| 9. (h) | Provision for the transfer of minimum information and coding information for retention to the care of a Human Application DI within the hospital, Trust or Board, or to another licensed establishment including the information referred to in Section D. | [ ]  Yes [ ]  No  |
| 9. (i) | Provision in relation to the transfer of the registers kept in accordance with the HTA Directions to the care of a Human Application DI within the hospital, Trust or Board, or to another licensed establishment or alternatively to the HTA. | [ ]  Yes [ ]  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 the care of a Human Application DI within the hospital, Trust or Board, or to another licensed establishment or alternatively transfer to the HTA. | [ ]  Yes [ ]  No  |
| 9. (k) | Provision for the transfer of any third party agreement to another licensed establishment or alternatively transfer to the HTA. | [ ]  Yes [ ]  No [ ]  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. | [ ]  Yes [ ]  No [ ]  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. | [ ]  Yes [ ]  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. | [ ]  Yes [ ]  No [ ]  N/A |
| **Please provide details of how this will be ensured:** |
| 10. | Records of traceability and raw data will be retained within the establishment, and marked for non-destruction for periods of 10 years (raw data) or 30 years (traceability) and appropriate facilities exist for that long term retention of records. | [ ]  Yes [ ]  No  |
| **Please provide details of how this will be ensured:** |

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

**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.

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| 11. | 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 the Q&S Regulations and paragraphs 18 and 19 of the Guide) . (This should be a provision of the third party agreement) | [ ]  Yes [ ]  No |
| **Please provide details of how this statutory requirement has been met:** |
| 12. | 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. | [ ]  Yes [ ]  No |
| 13. | 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.  | [ ]  Yes [ ]  No |
| 14. | 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 | [ ]  Yes [ ]  No |

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

Please confirm that the following documentation will be transferred to the care of a DI of another Human Application license at the 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 reactions) or will be retained on the premises in accordance with the requirements detailed in question 10 above.

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| **Records/documentation** | **Please tick** |
| **Registers**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. | [ ]  Yes [ ]  No |
| ii. A register of the coded data assigned to each donor and donation of tissues and cells.  | [ ]  Yes [ ]  No |
| **Donor and donation identification** (177a)That will include at least:i. Identification of the procurement organisation or establishment.ii. Unique donation identification number.iii. Date of procurement.iv. Place of procurement.v. Type of donation (for example single or multi tissue, autologous or allogeneic, living or deceased). | [ ]  Yes [ ]  No |
| **Product identification** (177b)That will include at least: i. Identification of the tissue establishment.ii. Type of tissue and / or cell / product (basic nomenclature).iii. Pool number (if applicable).iv. Split number (if applicable).v. Expiry date.vi. Tissue and / or cell status (i.e. quarantined, suitable for use etc).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.viii. Identification of the facility/establishment issuing the final label. | [ ]  Yes [ ]  No |
| **Human application identification** (177c)That will include at least:1. Date of distribution and/or disposal.
2. Identification of the clinician or end user /facility /establishment.
 | [ ]  Yes [ ]  No |
| **Where end use information is kept by the closing or terminating establishment:** i. Identification of the recipient.ii. Date of application. | [ ]  Yes [ ]  No |
| **Serious adverse events and reactions:**a. all records associated with serious adverse events or reactions | [ ]  Yes [ ]  No |
| 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 | [ ]  Yes [ ]  No |
| g. the SOP for the identification, investigation, reporting, recording and notification of serious adverse events and reactions | [ ]  Yes [ ]  No |
| h. the information provided to end users and other organisations responsible for human application about how to report serious adverse events and reactions.  | [ ]  Yes [ ]  No |

Please return this form by email to licensing@hta.gov.uk