



**Instructions for completing the HTA audit of relevant material  
removed from the deceased**

## **Who should use this document?**

- Any establishment which holds HTA licences for the making of a post-mortem examination and 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, is required to submit a summary of audit and inventory results to the HTA
- This does not apply to establishments that are storing tissue in the form of blocks and slides as part of an archive for NHS Trusts. Where this is the case, i.e. where relevant material is transferred to off-site storage establishments, the originating establishment is responsible for ensuring that this material is accounted for in the audit where appropriate.

## **Retention of relevant material from deceased persons**

Retention of relevant material, including tissue blocks and slides, for use for a scheduled purpose following the conclusion of a consented post mortem or the end of coroner/police authority requires appropriate and valid consent to be in place.

The HTA is aware that post mortem sector establishments may store tissue blocks and slides indefinitely as part of the medical record/medical archive. This is recommended under current Royal College of Pathology guidelines, and is consistent with the NHS and Department of Health consent forms and literature for post-mortem examination which date from 2003. The HTA considers that, retention in a medical record/archive is for potential use for a scheduled purpose(s) see below. Therefore, appropriate consent under the HT Act is required:

Scheduled Purposes under the HT Act 2004

1. anatomical examination
2. determining the cause of death
3. establishing after a person's death the efficacy of any drug or other treatment administered to him

4. obtaining scientific or medical information about a living or deceased person which may be relevant to any other person (including a future person)
5. public display
6. research in connection with disorders, or the functioning, of the human body
7. transplantation
8. clinical audit
9. education or training relating to human health
10. performance assessment
11. public health monitoring
12. quality assurance

### **Instructions for completing the audit of relevant material removed from deceased persons**

- Anyone working under an HTA licence can carry out the audit work; however, Designated Individuals should ensure that all required information is complete and accurate before submission to the HTA.
- You are not required to submit any records related to the audit other than the summary form. However, establishments must retain all audit records (hard copy and/or electronic copy) as these must be made available to the HTA upon request.

### **For establishments which transfer relevant material to external storage establishments**

The originating establishment is responsible for undertaking the audit; it should not be undertaken by storage establishments.

***This document is for guidance only. Model record-keeping forms and the results summary form which must be submitted to the HTA are available for download on the HTA website. Instructions for submitting the summary form will be available on the HTA website from 1 June. <http://www.hta.gov.uk/legislationpoliciesandcodesofpractice/htalegaldirections.cfm>***

## INVENTORY OF WHOLE ORGANS AND WET TISSUE

Whole organs and wet tissue removed from the body of a deceased person after 01 September 2006 and currently being retained must be inventoried. The record-keeping form shows you what information is required from the inventory exercise and is designed to aid you with the completion of the inventory. You are not required to use this form if you would prefer to create your own record keeping system. If you use this form, add as many rows as required to the table.

Download the form from the HTA website: <http://www.hta.gov.uk/legislationpoliciesandcodesofpractice/htalegaldirections.cfm>

For the purposes of the inventory, the following definitions apply:

Whole organs: all visceral organs, brains and whole fetuses over 24 weeks gestational age

Wet tissue: samples of visceral organs, brains, limbs, bone and fetal tissue over 24 weeks gestational age

In order to complete the inventory fully, you will need to refer back to the records of the post-mortem examination in order to establish why the material is being retained.

## INVENTORY FORM FOR WHOLE ORGANS AND WET TISSUE

*For use by the establishment only, not for submission to the HTA*

Item number	Item type A. Whole organ B. Wet tissue C. Limb D. Bone	Unique identifier	Description of item See definitions provided in guidance document	Location Room, floor, building, etc.	Reason for retention*
1					
2					
3					

*Add rows to the table as required.*

\* Reason for retention:

- A. Awaiting collection by Funeral Director or disposal – provide anticipated release disposal date/period (e.g. August 2010)
- B. Retained as part of the medical record (i.e. not for a specific scheduled purpose)
- C. Documented consent for use for one or more scheduled purpose – specify which purpose(s)
- D. Coroner’s authority ongoing
- E. No instruction from the family given to the Coroner or Hospital
- F. No instructions received from Coroner
- G. Retained under Police And Criminals Evidence Act (PACE) and no end date has been given / received
- H. Other – provide details

## AUDIT OF CASES WHERE TISSUE WAS RETAINED FOLLOWING POST MORTEM

For the period 1 July 2008 to 30 June 2009, the first 20% of cases in each month where tissue was removed during post-mortem examination and made into blocks and slides must be audited (you must provide information about all organs and tissue retained in these cases, not just the material which was made into blocks and slides). You are not required to use the record-keeping form if you would prefer to create your own record keeping system. If you use this form, add as many rows as required to the table. Download the form from the HTA website: <http://www.hta.gov.uk/legislationpoliciesandcodesofpractice/htalegaldirections.cfm>

The audit is large enough and sufficiently randomised for the results to be unlikely to be due to chance, i.e. the results will reflect actual properties of the traceability systems and allow generalisations about these systems to be made. Choosing cases for audit in a random manner avoids bias, and the number of cases audited must be large enough to ensure it is representative of the workload at each establishment. The time period chosen for the audit is considered to be sufficiently long after the commencement of the HT Act in September 2006 for there to be awareness of and compliance with the requirements and for the majority of Coroner and Police cases to have concluded.

### How to select cases for audit:

1. Count the total number of post-mortem examinations in each month from 1 July 2008 through 30 June 2009.
2. Identify the cases where organs and/or tissue were made into blocks (tissue may have been cassetted in the post mortem suite or may have been sent to a laboratory to be made into blocks).
3. Of the highlighted cases, select the first 20%. Where your calculation results in a decimal, always round up.  
*Example* Organs and/or tissue were retained following post mortem for further examination in 26 cases in February 2009. Twenty percent of 26 = 5.2; therefore include the first six of these cases in the audit.
4. There may be months where 20% of the cases for audit equals six or fewer (as in the example above). Where possible, a minimum of six cases should be included in the audit. If there are fewer than six cases which meet the audit criteria in a given month, then all of the cases which meet the audit criteria for that month should be included.

## AUDIT FORM FOR TISSUE RETAINED FOLLOWING POST MORTEM EXAMINATION

*For use by the establishment only, not for submission to the HTA*

### **SECTION 1: GENERAL INFORMATION**

<b>Unique case identifier</b> (e.g. post mortem number)	
<b>Date of post mortem</b> (DD/MM/YYYY)	
<b>Type of post mortem</b>	<input type="checkbox"/> Hospital <input type="checkbox"/> Coroner <input type="checkbox"/> Home Office
<b>Coroner name and district (where applicable)</b>	
<b>Coroners jurisdiction end date</b> (DD/MM/YYYY) (where applicable)	

## **SECTION 2: DETAILS OF RELEVANT MATERIAL**

<b>Item</b> (Use one row for each <b>type</b> of tissue which was retained following post mortem examination. Record '0' for block and slide totals where a piece of tissue or whole organ was retained but no blocks were made).		
1		Total number of wax blocks made:  Total number of slides made (indicate if not known):
2		Total number of wax blocks made:  Total number of slides made (indicate if not known):

Add rows to the table as required.

## **SECTION 3: CASE OUTCOMES**

<b>Item</b> (Corresponds to each item listed in the table in Section 2).	<b>Action taken (repatriation, released for burial/cremation, disposal, retained)</b>	<b>Date action carried out (DD/MM/YYYY)</b>	<b>Reason for retention* and further details **</b>	<b>Date consent was obtained, where applicable (DD/MM/YYYY)</b>
1				
2				
3				

Add rows to the table as required

\* Reason for retention:

- A. Awaiting collection by Funeral Director or disposal – provide anticipated release disposal date/period (e.g. August 2010)
- B. Retained as part of the medical record (i.e. not for a specific scheduled purpose)
- C. Documented consent for use for one or more scheduled purpose – specify which purpose(s)
- D. Coroner’s authority ongoing
- E. No instruction from the family given to the Coroner or Hospital
- F. No instructions received from Coroner
- G. Under Police And Criminals Evidence Act (PACE) and no end date has been given / received
- H. Other – provide details

\*\*Wishes for handling post mortem material may differ for different types of tissue. You will need to separate out all of the reasons for retention if there are differences within a given case.

Example A whole brain is to be repatriated with a body before release for burial, and any other samples taken during the post-mortem examination are to be disposed of.

Example A heart is to be donated for research, and any other samples taken during the post-mortem examination are to be retained in the medical record or disposed of.

## SUMMARY OF INVENTORY AND AUDIT RESULTS

You are not required to submit any of the records generated during the audit of retained material from deceased persons. If you do not use the record keeping forms provided for the inventory and audit exercises, refer to the summary form so you are aware of the information which will be required to be submitted to the HTA.

The HTA requires a summary of your findings to be submitted no later than 30 September 2010. **You must use the form provided. Add as many rows to each table as required. Download the form using the link below.**

Instructions about how to submit the summary form will be available on the HTA website from 1 June 2010.

<http://www.hta.gov.uk/legislationpoliciesandcodesofpractice/htalegaldirections.cfm>

## SUMMARY OF INVENTORY AND AUDIT RESULTS FOR SUBMISSION TO THE HTA

*You must complete all sections of this form and submit it to the HTA no later than 30 September 2010*

<b>Establishment name:</b>	
<b>HTA Licensing Number:</b>	
<b>Designated Individual (name and job title):</b>	

<b>GENERAL INFORMATION</b>		
A	Number of hospital post-mortem examinations completed between 1 July 2008 and 30 June 2009	
B	Number of coronial post-mortem examinations completed between 1 July 2008 and 30 June 2009 <i>Do not include Home Office cases in this tally.</i>	
C	Number of Home Office post-mortem examinations completed between 1 July 2008 and 30 June 2009	
D	When tissue is processed to prepare wax blocks, are the wet trimmings retained or disposed of as clinical waste?	

E	Number of whole organs and items of wet tissue which date from 1 September 2006, which are stored off-site (i.e. at a separate licensed establishment)	
F	Number of tissue blocks from the audited cases which are stored off-site (i.e. at a separate licensed establishment)	

<b>INVENTORY OF WHOLE ORGANS AND WET TISSUE</b>		
A	Number of whole organs currently being retained, which date from 1 September 2006 onwards <i>Do not include whole fetuses in this tally.</i>	
B	Number of items of wet tissue currently being retained, which date from 1 September 2006 onwards <i>Do not include fetal tissue in this tally.</i>	
C	Number of whole fetuses and items of fetal tissue currently being retained, which date from 1 September 2006 onwards	
D	Number of cases for which you were unable to locate any documentation relating to retention	
E	Number of cases for which you have incomplete documentation relating to retention	
F	How many of the cases in 'D' and 'E' were hospital cases?	
G	How many of the cases in 'D' and 'E' were coronial (including Home Office) cases?	
H	Number of cases for which the documentation relating to retention indicates that you should not be retaining the organ/issue (this means that you have identified an item in storage but the related paperwork indicates a request for repatriation to a body/return for burial or cremation/disposal).	
I	How many of the cases in 'H' were hospital cases?	

J	How many of the cases in 'H' were coronial (including Home Office) cases?	
K	How many whole organs and items of wet tissue are you currently retaining under coroner or police authority? <i>Include whole fetuses and items of fetal tissue in this tally.</i>	
L	How many whole organs and items of wet tissue are you currently retaining while awaiting disposal or collection for burial/cremation? <i>Include whole fetuses and items of fetal tissue in this tally.</i>	
M	How many whole organs and items of wet tissue are you currently retaining with consent for use for a scheduled purpose? <i>Include whole fetuses and items of fetal tissue in this tally.</i>	
	<i>Use this space to list all of the scheduled purposes for which you are currently retaining whole organs and wet tissue. Expand the space as required.</i>	
	<i>Use this space to provide any additional information which is relevant to your current retention of whole organs and wet tissue. Expand the space as required.</i>	

<b>AUDIT OF TISSUE RETAINED FOLLOWING POST MORTEM EXAMINATION</b>		
A	Total number of tissue blocks originally generated from the audited cases	
B	Number of audited cases where organs, tissue, or blocks and/or slides are still being retained	
C	Number of audited cases for which you were unable to locate any documentation relating to retention	
D	Number of audited cases for which you have incomplete documentation relating to retention	
E	How many of the cases in 'C' and 'D' were hospital cases?	
F	How many of the cases in 'C' and 'D' were coronial (including Home Office) cases?	
G	Number of audited cases for which the documentation relating to retention indicates that you should not be retaining the organ/issue (this means that you have identified an item in storage but the related paperwork indicates a request for repatriation to a body/return for burial or cremation/disposal).	
H	How many of the cases in 'G' were hospital cases?	
I	How many of the cases in 'G' were coronial (including Home Office) cases?	
J	Select the phrase which most accurately reflects traceability of slides during the audit. Were you able to trace:	

	<p>All of the slides (100%)  Most of the slides (more than 75%)  Some of the slides (30 – 75 %)  Few of the slides (less than 30%)</p>	
	<p><i>Use this space to list all of the scheduled purposes for which you are currently retaining whole organs and wet tissue. Expand the space as required.</i></p>	
	<p><i>Use this space to provide any additional information which is relevant to your current retention of whole organs and wet tissue. Expand the space as required.</i></p>	