POLICY DOCUMENT

Burton Hospitals
NHS Foundation Trust

POLICY FOR THE DISPOSAL OF HUMAN TISSUE OBTAINED DURING A POST MORTEM PROCEDURE

Approved by:	**Trust Executive Committee**
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Burton Hospitals NHS Foundation Trust

POLICY INDEX SHEET

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REVIEW AND AMENDMENT LOG

Version	Type of change	Date	Description of Change
4		14.02.2013	Change in titles
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1. MISSION AND POLICY STATEMENT

The Trust aims to adhere to legislation introduced in 2004 as part of the Human Tissue Act, for the sensitive and dignified disposal of tissues and other relevant material removed from a deceased person. These processes will be regulated by The Human Tissue Authority, which is introduced in the Act as a regulatory body for the removal, storage, use and disposal of human tissues, excluding gametes and embryos, for use in a scheduled purpose, other than transplantation.

This Policy has been introduced for compliance to the Human Tissue Act 2004, which extends to England, Wales and Northern Ireland. The Act introduced new legislation for the removal of tissue and organs from the dead, and the use and storage of such tissues and organs. Storage and use of tissues obtained from the living are also covered by the Act, which repeals and replaces earlier acts, as they relate to England, such as the Human Tissue Act, 1961, the Anatomy Act, 1984, and the Human Organ Transplant Act, 1989.

This Trust has gained a licence under the Human Tissue Act 2004, for the making of a post mortem examination, the removal of relevant material from the body of a deceased person for use in a scheduled purpose, and the storage of this relevant material, or body, for use in a scheduled purpose (licence number 12317). The Mortuary Anatomical Pathology Technicians (APT) and Designated Individual will play a lead role in ensuring that all activities covered by this licence are undertaken by the Trust according to guidelines and codes of good practice issued by the Human Tissue Authority. The Trust, through its management, will also be encouraged to promote and facilitate the sensitive and dignified disposal of any tissue or relevant material from deceased persons.

2. AIMS & OBJECTIVES

This Policy aims to follow guidelines and good practice procedures recommended by the Human Tissue Authority for the sensitive and dignified disposal of human tissue from the deceased.

The Disposal Policy seeks to:

- Ensure that all medical and non-medical personnel involved in the process of consent for post mortem have received the appropriate training, and that appropriate records are maintained.
- Ensure that appropriate consent is obtained before any post mortem examination is undertaken, unless the examination is at the request of the Coroner.
- Ensure that this consent includes whether agreement for the removal of tissues for a scheduled purpose has been given. If agreement has been given an option for storage or disposal of these tissues **must** be given.
- Ensure that at the end of the scheduled purpose, or when the Coroner no longer requires the material, that it is stored or disposed of according to the wishes of the deceased relatives.
- Ensure that the disposal of this material is carried out in a sensitive and dignified manner following Trust SOPs.

At all times during the consent process, relatives of the deceased **must** be informed of the exact procedures that will take place. At all times the wishes of the deceased's relatives **must** be adhered to.

Still born fetuses and intra partum losses subject to specialist post mortems are performed at Birmingham Women's Hospital (see Policy **Transportation of Babies For Post Mortem to The Mortuary at Birmingham Women's Hospital).** Disposal of any tissue removed therefore will be subject to the referral hospital's Disposal Policy.

3. SCHEDULE OF DEFINITIONS

3.1 Designated Individual

The individual designated in the licence as the person under whose supervision the licensed activity is authorised to be carried on. This person is responsible for securing that other persons to whom the licence applies are suitable persons; that suitable practices are carried out in the course of carrying on the licensed activity and for compliance with the conditions of the licence. The HTA must be satisfied as to the suitability of this person.

3.2 Licensed Premises

Where the licensed activity (e.g. making of a post mortem examination, storage, or public display) takes place. If the licensed activity will take place at more than one place, a separate licence will need to be issued. Premises in different streets or with different postal codes will be considered as being in different places. In contrast, different buildings on a hospital site could be regarded as the same place.

3.3 Licensing

A number of activities can only be carried out where the establishment is licensed under the Act by the HTA for that purpose. The activities are:

- The carrying out of an anatomical examination;
- The making of a post mortem examination;
- The removal from the body of a deceased person (otherwise than in the course of the activities mentioned above) of relevant material of which the body consists or which it contained, for use for a Scheduled Purpose other than transplantation;
- The storage of an anatomical specimen;
- The storage (other than of an anatomical specimen) of the body of a deceased person or relevant material which has come from a human body for use for a Scheduled Purpose;
- The use, for the purpose of public display of the body of a deceased person, or relevant material which has come from the body of a deceased person.

3.4 Licence Holder

The person who applies for and is granted a licence who can be, but is not necessarily the Designated Individual. The Licence Holder is responsible for the payment of any fees charged by the HTA including fees charged in respect of superintending compliance with licences and any other fees as specified by the HTA from time to time. The Licence Holder can be a corporate body.

Where the applicant is not the proposed Designated Individual, the HTA must be satisfied that the applicant is a suitable person to be the holder of the licence.

3.5 Post Mortem

Post Mortem means dissection and examination of a body after death, principally in order to determine the cause of death, or the presence of disease processes. A hospital post mortem examination is carried out with appropriate consent to gain a fuller understanding of the deceased person's illness or the cause of death, and to enhance future medical care. Coroners' post mortem examinations are carried out under the authority of the coroner and without consent to assist coroners in carrying out their functions. Coroners' post mortems are carried out in accordance with the provisions of the Coroners Act 1988 and the Coroners Rules 1984 (amended 2005) and the Coroners Act (Northern Ireland) 1959, and the Corners (Practice and Procedure) Rules (Northern Ireland) 1963.

3.6 Relevant Material

Relevant material is defined by the Act as material other than gametes, which consists of or includes human cells. In the Act, references to relevant material from the human body do not include:

(a) embryos outside the human body, or

(b) hair and nail from the body of a living person.

3.7 Scheduled Purposes

Scheduled Purposes are the activities relating to the removal, storage and use of human organs and other tissue, listed in Schedule 1 of the Act that require consent. The Purposes are divided into two parts:

<u>Part 1: Purposes Requiring Consent: General</u>

- Anatomical examination
- Determining the cause of death
- Establishing after a person's death the efficacy of any drug or other treatment administered to him
- Obtaining scientific or medical information about a living or deceased person which may be relevant to any other person (including a future person)
- Public display
- Research in connection with disorders, or the functioning, of the human body
- Transplantation

Part 2: Purposes Requiring Consent: Deceased Persons

- Clinical audit
- Education or training relating to human health
- Performance assessment
- Public health monitoring
- Quality assurance

4. KEY PROCEDURES

Key procedures in delivery of this Policy include:

- To ensure that medical and non-medical personnel involved in the consent process for post mortem examination are appropriately trained, and that appropriate records are maintained.
- To ensure that all technical personnel involved in the making of a post mortem are appropriately trained and are familiar with the variables of the consent process.
- To ensure that all technical personnel involved in the sensitive and dignified disposal of relevant material removed from a deceased person are appropriately trained and adhere to current SOPs issued by the Trust.
- That all personnel involved act under the Codes of Good Practice issued by the Human Tissue Authority, and guided by the Designated Individual.
- That at all times Standard Operating Procedures are followed and risk assessments are in place for all procedures.
- That documentation for consent for post mortem clearly defines options for the removal of tissue and what this tissue may be used for. Disposal and storage options for the removed tissue must also be clearly defined.

5. MANAGEMENT ARRANGEMENTS

- The Policy will be determined by, and implemented under the authority of the Board of Directors.
- All personnel involved will work under the guidance of the designated individual, in accordance with guidelines and codes of good practice issued by the Human Tissue Authority.

6. DUTIES AND RESPONSIBILITIES

6.1 Board of Directors

- The Board of Directors shall ensure that all personnel required to take consent are appropriately trained and that accurate training records are maintained.
- Ensuring that appropriate Standard Operating Procedures are in place for all steps of the consent for post mortem procedure, and for the sensitive and dignified disposal of human tissue obtained from deceased persons, and that all personnel adhere to them.

6.2 Designated Individual

The individual designated in the licence as the person under whose supervision the licensed activity is authorised to be carried on. This person is responsible for securing that other persons to whom the licence applies are suitable persons; that suitable practices are carried out in the course of carrying on the licensed activity and for compliance with the conditions of the licence. The HTA must be satisfied as to the suitability of this person.

The Designated Individual shall:

- Ensure that Standard Operating Procedures are in place detailing the procedure for providing information on consent and for the consent process.
- Ensure that all staff involved in seeking consent are appropriately trained for taking Post Mortem consent, taking into account the requirements of the HTA Code of Practice on Consent. Training records should be kept.
- Shall ensure that an updated Policy is in place, and made available to the public, for the sensitive disposal of human tissue. The Policy should cover the requirement of staff to follow the consent requirements with regards to disposal and document the reasons and methods used.
- Shall complete HTA accredited training as specified by the HTA on the HTA website or as may be set out in Directions. This must be completed within a period of twelve months from the date of issue of the licence or such other period as may be specified by the HTA in Directions.
- Shall advise the HTA immediately they become aware of any proposal or decision to close the licenced premises.
- Shall offer advice and guidance to all personnel involved in the taking of consent for post mortem, the post mortem procedure itself and in the dignified and sensitive disposal of human tissue obtained during post mortem.
- Will be responsible for the implementation of any changes to procedures that the Human Tissue Authority deem necessary.

- Shall liaise with The Human Tissue Authority regarding any adverse incidents that occur relating to the procedures outlined in this Policy.

6.3 Clinical Directors / Associate Directors / Identified Line Manager

- That all personnel involved in the post mortem process and the disposal of human tissue from deceased persons have received the appropriate training.

- Accurate records must be maintained at all stages of the consent and post mortem procedures, and these must be subject to regular audit.

- Appropriate risk assessments are in place for all activities involved in the taking of consent for post mortem and of all post mortem procedures.

6.4 Personnel involved in seeking Consent for Post Mortem

- Personnel should not take part in seeking consent for post mortem unless they have received the appropriate training from the Trust.

- Standard Operating Procedures must be adhered to at all times.

- Personnel involved in taking consent for post mortem should ensure that they use the correct documentation, and that all parts of the forms are filled in correctly.

- At all times, procedures should be explained clearly to relatives of the deceased to ensure that they understand exactly what is involved.

- Any adverse incidents occurring during the whole process must be brought to the attention of the Designated Individual, who will then liaise with the Human Tissue Authority.

6.5 Pathologist

- Only appropriately trained medical personnel may undertake a post mortem procedure.

- The pathologist undertaking the post mortem is responsible for the correct interpretation of the wishes of the relatives of the deceased as to the removal of tissue during the post mortem procedure. Permission for the removal of tissue from a deceased person should be clearly outlined during the consent process.

- At all times the pathologist should act according to guidelines and codes of good practice issued by the Human Tissue Authority. The Designated Individual can assist in the implementation of these guidelines.

- Any adverse incidents occurring during the whole process must be brought to the attention of the Designated Individual, who will then liaise with the Human Tissue Authority.

6.6 Mortuary Technical Personnel

- Only appropriately trained personnel may assist in the making of a post mortem. At all times Standard Operating Procedures must be followed.
- Mortuary personnel should be aware of the consent process, and should adhere to the wishes of the deceased's relatives as to the removal of tissue for a designated purpose.
- At all times, mortuary personnel shall work under the supervision of the Designated Individual and according to the guidelines and Codes of Good Practice issued by the Human Tissue Authority.
- Any adverse incidents occurring during the whole process must be brought to the attention of the Designated Individual, who will then liaise with the Human Tissue Authority.
- Only appropriately trained Mortuary personnel or the DI should undertake the disposal of human tissue obtained during the post mortem procedure, following Standard Operating Procedures issued by the Department of Histology for sensitive and dignified disposal.
- Disposal of human tissue from post mortem procedures will be done according to the wishes of the deceased's relatives, or on the order of the Coroner.
- Shall ensure that in all cases appropriate documentation is in place, which can be easily audited.
- At all times Mortuary personnel involved in the sensitive and dignified disposal of human tissue from deceased persons shall work under the guidance of the Designated Individual and according to Codes of Good Practice issued by the Human Tissue Authority.
- Any adverse incidents occurring during the whole process must be brought to the attention of the Designated Individual, who will then liaise with the Human Tissue Authority.

7. SUPPORT, HELP AND FURTHER ADVICE

Further support, help or advice can be obtained by contacting the Human Tissue Authority at www.hta.gov.uk.

Additional information can also be obtained from the Trust's Designated Individual for the Human Tissue Act – Mark Adams,. Operations Manager Medicine

8. EFFECTIVENESS OF POLICY

This Policy will be reviewed and updated at regular intervals to ensure the Trust's continuing compliance with the Human Tissue Act, 2004. Amendments will be made by the Designated Individual to ensure that the Trust continues to adhere to guidelines and codes of good practice issue by the Human Tissue Authority.