

## Document Control

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**CONTENTS**

<b>1. Purpose .....</b>	<b>3</b>
<b>2. Definitions .....</b>	<b>3</b>
<b>3. Responsibilities .....</b>	<b>6</b>
<b>4. Policy and Guidelines .....</b>	<b>7</b>
4.1 Hospital Post Mortem Examination on an Adult .....	7
4.2 Consent Process .....	8
4.3 Formal Documentation .....	8
4.4 Tissue Retention .....	9
4.5 Coroner’s Post Mortem Examination .....	10
4.6 Post Mortem Examinations of Children or Infants .....	11
4.7 Post Mortem Examinations on Late Gestation (12/40 and above) Foetal Remains, Stillbirths and Neonatal Deaths.....	12
4.8 Foetal Remains up to 23 weeks and 6 days gestation .....	12
4.9 Funeral Arrangements/Sensitive Disposal .....	13
4.10 Funeral arrangements for Foetal Remains up to 23 weeks and 6 days gestation .....	13
4.11 Funeral Arrangements for Stillbirths and Neonatal Deaths.....	13
4.12 Sensitive Disposal Following a Termination of Pregnancy .....	14
4.13 Existing Holdings .....	14
4.14 Tissue Obtained During the Course of Medical Treatment .....	14
<b>5. Monitoring Compliance with and the Effectiveness of the Policy .....</b>	<b>16</b>
5.1 Standards / Key Performance Indicators .....	16
5.2 Process for Implementation and Monitoring Compliance and Effectiveness .....	16
<b>6. Equality Impact Assessment.....</b>	<b>17</b>
<b>7. References .....</b>	<b>17</b>
<b>8. Associated Documentation .....</b>	<b>18</b>

## 1. Purpose

The purpose of this document is to provide information and guidance about Northern Devon Healthcare Trust's approach to post mortems, sensitive disposal choices and funerals following pregnancy loss, and the retention and disposal of human tissue following a post mortem or taken during the course of medical treatment.

The information is for health care professionals, the public, bereaved relatives, patients and families.

The policy will ensure that:

- Bereaved relatives are treated with respect and sensitivity at all times to help them take difficult decisions around the issue of post mortem examinations.
- Consent and awareness are the underlying principles for carrying out hospital post mortem examinations.
- Consent and awareness are the underlying principles for the retention, storage and disposal of post mortem tissue samples.
- Patients are aware of what happens to tissue taken during the course of medical treatment.
- The options for sensitive disposal and funerals following a pregnancy loss are appropriate and meet the need of the patient.
- Northern Devon Healthcare Trust has an open and honest approach to dealing with the issue of post mortems, sensitive disposal following pregnancy loss and retained tissue.
- All trust staff involved in these activities comply with the regulations of the Human Tissue Act, the codes of practice published by the Human Tissue Authority and the license issued to Northern Devon Healthcare Trust by the Human Tissue Authority.

## 2. Definitions

### Human Tissue Act 2004

The legal framework for the storage and use of tissue from the living and for the removal, storage and the use of tissue and organs from the deceased for scheduled purposes.

### Human Tissue Authority

The regulatory body for all matters concerning the removal, storage, use and disposal of human tissue.

### Human Tissue Authority Codes of Practice

Codes of practice that give practical guidance to those carrying out activities within the HTA's remit.

### Designated Individual (DI)

This is the person at the Trust required for the Post Mortem establishment licence issued by the regulatory body, the Human Tissue Authority.

At Northern Devon Healthcare Trust, Lee Luscombe, the Pathology Service Manager is DI.

Lee can be contacted at [lee.luscombe@nhs.net](mailto:lee.luscombe@nhs.net) for advice, guidance and information in regard to Post Mortems

Designated Individuals have a key role to play in implementing the requirements of the Human Tissue Act. They are the person under whose supervision the licensed

activity, post mortems, is authorised to be carried out. They have the primary (legal) responsibility under Section 18 of the Human Tissue Act to secure:

- that suitable practices are used in undertaking the licensed activity;
- that other persons working under the licence are suitable and;
- that the conditions of the licence are complied with.

The Designated individual is responsible for ensuring there is a suitable consent procedure in place that meets the requirement of the Human Tissue Act and the standards and codes of practice issued by the Human Tissue Authority.

### **The Coroner**

An independent judicial officer responsible for investigating death.

### **Coroner's Office**

H M Coroner for Exeter and Greater Devon and representatives, (HM Coroners Officers).

### **Coroner's Post Mortem**

A post mortem examination ordered by the Coroner carried out to assist the Coroner in the investigation of a death.

### **Hospital Post Mortem**

This is a post mortem examination which aims to find out more about a person's illness and cause of death. It can only be carried out with the prior consent of the deceased person, the consent of their nominated representative or a person in a qualifying relationship. The person giving consent is able to limit the post mortem examination, make particular requests to what tissue is retained and to what it can be used for.

### **Nominated Representative**

A person nominated by the deceased, empowered to consent to a post mortem examination and the removal of tissue for a scheduled purpose.

### **Qualifying Relationship**

If the deceased person has not indicated their consent or refusal to a post mortem, or appointed a nominated representative, then consent can be given by someone in a qualifying relationship with the deceased immediately before their death. Those in a qualifying relationship are in the following order, highest first.

- Spouse or partner (including civil and same sex partners)
- Parent or Child
- Brother or Sister
- Grandparent or Grandchild
- Stepfather or Stepmother
- Half-brother or half sister
- Friend of long standing

Consent is needed from only one person in the hierarchy of qualifying relationships and should be obtained from the person ranked highest. If a person ranked highest in the list refuses to give consent, it is not possible to act on consent from someone further down the list.

### **Scheduled Purposes**

These are activities that relate to the removal, storage and use of human tissue that require consent.

General purposes requiring consent:

- Anatomical examination
- Determining cause of death
- Establishing after death the efficacy of any drug or other treatment administered to them e.g. a hospital post mortem
- Obtaining scientific or medical information about a living or deceased person which may be relevant to another person- e.g. genetic information
- Public display
- Research in connection with disorders or the functioning of the human body
- Transplantation

For deceased persons these also include:

- Clinical Audit
- Education or Training relating to human health
- Performance assessment
- Public health monitoring
- Quality assurance

### **Consent**

The expressed wishes or permission given voluntarily by an individual or a person in a qualifying relationship when appropriately informed about the storage, use and disposal of tissue obtained during the course of medical treatment and post mortem examination.

### **Tissue**

Means any and all constituent part(s) of the human body formed by cells. This will include whole organs, tissue blocks, tissue slides and all body fluids.

### **Tissue from the Living**

This is tissue taken during the course of medical treatment or in the course of a diagnostic procedure.

### **Tissue from the Deceased**

This is tissue samples taken during a post mortem examination that are used to understand illness and the cause of death.

### **Wet Tissue**

This is formalin preserved whole organs or representative parts of organs removed during the course of medical treatment or a post mortem examination.

### **Tissue, Samples, Blocks & Slides**

Samples of tissue are taken from various organs to understand an illness or the cause of death. The samples are made into hard wax blocks, approximately 2cm across and 5mm thick. From these blocks very thin sections, about 10 times thinner than human hair, can be cut. These are placed on a glass slide so that they can be examined under a microscope. More than one section can be cut from one block.

### **Medical Research**

Creating new knowledge about disease and new treatments for disease through the examination and testing of tissue.

### **Medical Record**

In the context of this policy this will mean that the tissue will be stored by Northern Devon Healthcare Trust as part of the individual's medical record. Its use in the

future to obtain medical information or research relevant to the individual or any other person connected to the individual will require consent.

### **Quality Control Material**

Tissue used for quality assurance, a process of monitoring and evaluating diagnostic tests in a laboratory. It ensures that standards of quality are maintained.

### **Sensitive Disposal**

Disposal of pregnancy remains by an appropriate method, usually cremation or burial that meets the need of women experiencing pregnancy loss.

### **Clinical Disposal**

Disposal of tissue by incineration.

### **Existing Holdings**

Relevant material which has come from a human body held immediately prior to the commencement of section 1 of the Human Tissue Act 2004 for a Scheduled purpose. For the purpose of this policy it refers to tissue blocks and slides obtained during the course of post mortem examinations before the 1st of September 2006.

### **Late Foetal Loss**

In the context of this policy relates to fetuses/foetal tissue and products of conception from a pregnancy of up to 23 weeks + 6 days gestation that shows no signs of life at delivery. It includes ectopic pregnancies, miscarriages and early intrauterine deaths.

### **Stillbirth**

In the context of this policy relates to an infant at 24 weeks or greater gestation dying before or during the delivery and who is born with no signs of life.

### **Neonatal Death**

In the context of this policy relates to a baby born alive and dying within 28 days of delivery or when the foetus/baby irrespective of gestation breathes or shows any other evidence of life such as beating of the heart, pulsation of the umbilical cord or any definite movement of voluntary muscles whether or not the umbilical cord has been cut or the placenta is attached (NMC 2007). These cases must be reported to the Coroner.

## **3. Responsibilities**

### **The Designated Individual**

This person is responsible for those activities covered by the Human Tissue Authority licence issued to Northern Devon Healthcare Trust.

### **Licence Holder**

Northern Devon Healthcare Trust is responsible for ensuring that adequate resources are available to comply with The Human Tissue Act 2004 and the Human Tissue Authority licence issued to it. The deputy Chief Operating Officer is the named Executive lead for this.

### **Person Seeking Consent to a Medical Procedure**

Is responsible for ensuring that the patient is aware of what will happen to the tissue removed in the course of their treatment. They will, when asked, inform the patient of

the existence of this policy and the options available to them in regard to the retention, use of and disposal of tissue samples.

#### **Person/s Seeking Consent to a Hospital Post Mortem**

Are responsible for ensuring consent is valid, i.e. given voluntarily, by an appropriately informed person who has the capacity to agree to a post mortem examination. They are responsible for following this policy and the Northern Devon Healthcare Trust procedures for obtaining consent to a hospital post mortem.

#### **Coroner's Office**

Will obtain consent from an appropriate person for the retention or disposal of tissue obtained during a coroners post mortem following the conclusion of the Coroner's investigations.

#### **Consultant Pathologist**

The consultant pathologist will discuss with the doctor seeking consent, about the scope of the post mortem and the need for tissue retention. They will ensure the appropriate consent is in place before a post mortem examination.

#### **Pathology Service Manager**

This person will ensure that there is good control of procedures in the Laboratory and Mortuary in relation to this policy.

#### **Bereavement Support Office**

The Bereavement Support Office will support and advise relatives of the deceased on the issues raised in this policy.

## **4. Policy and Guidelines**

### **4.1 Hospital Post Mortem Examination on an Adult**

The consultant in charge of the deceased during their last illness will make a decision about consideration for a hospital post mortem examination, knowing the medical problems and the unresolved aspects that merit investigation. They will discuss the case with a consultant pathologist to determine if it is appropriate.

Hospital post mortems will only be carried out with the prior consent of the deceased, consent from their nominated representative or consent from a person in a qualifying relationship with the deceased immediately before their death.

The Northern Devon Healthcare Trust procedure for obtaining consent for hospital post mortems must be followed.

Consent is only valid if it is given voluntarily by an appropriately informed person, who has the capacity to agree to a post mortem examination.

#### **First Steps**

- The consultant (or delegated member of the medical team, ideally a person with whom the family have established a relationship) will determine in a sensitive way, being honest and clear, providing objective information whether the family are willing to discuss consent. Once this has been established they will make arrangements with the Bereavement Support Office to formally obtain consent.

- Consent taking is a team approach between the doctor and a member of the Bereavement Support Team with knowledge of post mortem procedures and trained to take consent. They will answer questions openly and honestly providing the family with all the information they require.
- The team will establish who the appropriate person to give consent is. In order of priority:
  1. Has the deceased specifically expressed a wish for or against a post mortem?
  2. Has a nominated representative to take such a decision been appointed by the deceased. You will need to verify their authority.
  3. The highest ranked person in a qualifying relationship.
- Discussion between family members and a consensus decision will be encouraged.
- Where there is disagreement between family members decisions will need to be made on a case by case basis taking into account the view of the most appropriate person to give consent.
- If the most appropriate person does not wish to deal with the issue of consent, they are not able to deal with the issue or they cannot be located in a reasonable time the next person in the hierarchy will become the appropriate person to give consent.
- Consent will be taken sensitively, face to face in a private room.

#### 4.2 Consent Process

Sufficient information will be provided to ensure valid consent is obtained. The person giving consent will be given an information booklet to read and time to ask questions beforehand. Those taking consent will:

- Explain why a post mortem should be performed, the benefits of the examination, the medical problems to be investigated further, with clear objective information, the limitations and that it may not provide answers.
- Explain what happens in a post mortem examination, giving as much information as the family require. Some will wish to know considerable details; others will not want to know any details.
- Discuss possible alternatives to a full post mortem, making clear the limitations of these compared to a full post mortem.
- Explain what tissue/samples will need to be retained for further examination. Explain the purpose of the examinations and what they involve.
- Explain what will happen to the body and the options available for the disposal of tissue removed during the post mortem examination.
- Explain fully the implications on the available options, for example the possible delay to funeral arrangements if a whole organ needs to be examined and the person giving consent requests that it is returned to the body.
- Give the family the opportunity to ask questions and talk to anyone else they feel will be able to help them.
- Give them reasonable time in private, to reach a decision.

#### 4.3 Formal Documentation

Written, witnessed consent is obtained before any hospital post mortem examination. The consent forms allow for the accurate recording of the discussions that have taken place and the wishes of those giving consent to the post mortem. **We comply with the consent documented in consent forms at all times.** The person giving consent is given:

- A copy of the completed consent form.
- Information leaflets about the post mortem examination.
- Bereavement Support Office and mortuary contact details.
- The time and place the post mortem is scheduled to take place.
- A time by which they will need to contact the Bereavement Support Office or Mortuary if they change their mind. Consent can be withdrawn at any time up until the post mortem is scheduled to take place.
- The option of changing their mind about any other aspect of the consent they have given, e.g. tissue disposal.
- Information on when the results are likely to be available and arrangements to allow them, if they so wish, to discuss the results with the clinician. They can opt to receive the information in a letter.
- A date by which the Bereavement Support Office will contact them to ensure the post mortem results have been made available to them or to update them on progress if they are not yet available.

Care will be taken not to disclose sensitive information or medical history that the deceased may not wish to have disclosed or could have implications for other family members. The doctor makes a decision based on individual circumstances as to whether it is appropriate or not to disclose such information. They will be guided by GMC guidance on confidentiality and the policies of Northern Devon Healthcare Trust.

Staff must be sensitive to different cultures and religions, information upon which can be found in the Last Offices - Standard Operating Procedure (& Care After Death following a death in Hospital) SOP No. 09/060. However the decision in regard to a post mortem examination is a personal one and thus is treated as such.

When the first language of an individual or family is not English and for sign language users the Bereavement Support Office will follow the Northern Devon Healthcare Trust Interpretation and Translation policy to ensure proper communication takes place.

The consultant Pathologist checks the consent documents for a hospital post mortem examination before the post mortem and only retains tissue, if necessary, in accordance with the consent.

#### **4.4 Tissue Retention**

In the majority of cases only standard Histology block sized tissue samples will be retained. However occasionally it may be necessary to retain larger tissue samples or whole organs for fixation and subsequent careful dissection. Occasionally it is necessary to refer tissue/organs to another centre for examination. This should be discussed during the consent process.

Disposal of the tissue samples is in accordance with the wishes of the person giving consent. They are fully informed during the consent process of all of the options available and the benefits of each. The options are:

- Consent can be given for the subsequent retention of tissue for scheduled purposes and/or part of the medical record.
- The tissue can be returned to the body, however subsequent examination processes can take several weeks so it can delay any funeral arrangements. They will be advised specifically how long the delay is likely to be depending on the tissue and examinations required and the implications of prolonged holding of the deceased at the mortuary.

- Hospital clinical disposal.
- The tissue can be returned to a funeral director for lawful disposal at a later date, (e.g. burial or cremation).

These options are discussed fully during the consent process.

The terms of consent are followed at all times as long as the wishes expressed are reasonable and lawful.

Anyone giving consent to retain tissue can change their mind at any time. Northern Devon Healthcare Trust will act accordingly to any future requests in regard to tissue storage, use and disposal.

All tissue is labelled with unique laboratory identification numbers and accurate records are kept to ensure traceability.

#### **4.5 Coroner's Post Mortem Examination**

Coroner's post mortem examinations enable Coroners to carry out their statutory function to determine the identity of the deceased person and the cause of death. Coroners are empowered to authorise a post mortem following any sudden death of unknown cause or unexpected death.

A post mortem and the removal and storage of relevant material to determine the cause of death do not require consent if they are authorised by the Coroner. The Coroner will stipulate what material can be stored and for how long. This will usually be until the end of the Coroner's investigations and the conclusion of the inquest. Consent to retain tissue will be sought from the Coroner by the Consultant Pathologist.

All tissue held for the Coroner is labeled with unique laboratory identification numbers and accurate records are kept to ensure traceability.

The Bereavement Support Office provides relatives with general information about Coroner's post mortems and signposts families to the Coroner's Office for further information.

Mortuary facilities are provided for H M Coroner for Exeter and Greater Devon. Post mortems are carried out upon the receipt of instructions from the Coroner. Tissue is only retained from Coroner's post mortems with the consent of the Coroner for the period of time stipulated. This is usually until the conclusion of the Coroner's investigations and the completion of an inquest.

To retain tissue for a scheduled purpose after this time the specific consent of someone in a qualifying relationship is required.

The Coroner's Office will inform the family that tissue has been retained and asks the highest ranked person available what they would like to happen to the tissue when it is released by the Coroner.

The options are:

- Subsequent retention of tissue for scheduled purposes and/or part of the medical record.

- The tissue can be returned to the body, however subsequent examination processes can take several weeks so it can delay any funeral arrangements. They will be advised specifically how long the delay is likely to be depending on the tissue and examinations required.
- Hospital clinical disposal.
- The tissue can be returned to a funeral director for lawful disposal at a later date, (e.g. burial or cremation).

The wishes of the family are recorded on a tissue retention/disposal form and forwarded to the laboratory. Once released the laboratory acts in accordance with the family's wishes.

If the laboratory receives no instructions; in the first instance the Coroner's Office is contacted to obtain the required information. If the family do not make their wishes known or there is no appropriate person to complete the form the tissue will be disposed of within 3 months of release by the Coroner by clinical disposal.

#### **4.6 Post Mortem Examinations of Children or Infants**

##### **Coroner's cases**

Post mortem examinations on children or infants (28 days to 18 years old) are referred to a specialist centre. We support Coroner's cases by caring for the body before transfer and when they are returned to North Devon, following the post mortem, until such time as the family makes funeral arrangements.

It is a statutory requirement that pathology specimens are removed from deceased infants and children for microbiological, biochemical and toxicological testing in cases of unexplained death in infancy as defined in the Government publication Working Together to Safeguard Children (March 2015). In such cases the Coroner has given general approval, as set out in the Protocol for Peninsula Child Death Overview to take material for investigations. As with adult post mortems retained material will only be retained for the period set by the Coroner.

##### **Hospital cases**

The consultant caring for a deceased infant or child during their last illness will make a decision about consideration for a Hospital post mortem examination, knowing the medical problems and the unresolved aspects that merit investigation.

They must contact the Bereavement Support Office to make arrangements to seek consent as for adults. However there are certain difficulties and sensitivities to consider. The post mortem examinations are performed at a specialist center, usually at St Michaels Hospital in Bristol. This introduces delays as it can take a couple of weeks before the child is returned to North Devon. This is discussed with the parents during the consent process and the implications of any decisions they may make explained to them. From this they will be able to make informed choices when giving consent.

The Bereavement Support Office and mortuary make the necessary arrangements, caring for the deceased before transfer and when they are returned to North Devon, following the post mortem, until such time as the family makes funeral arrangements. During this time they provide information and support to the family.

As for adult post mortems the clinician must first establish a willingness to discuss consent with the parents or those with parental responsibility for the child. If there is no one with parental responsibility then consent will be sought from someone in a qualifying relationship. In law a child can be considered competent to give consent

before they have died however this would be rare in practice and Northern Devon Healthcare Trust will always discuss consent with parents and consider their needs.

#### **4.7 Post Mortem Examinations on Late Gestation (12/40 and above) Foetal Remains, Stillbirths and Neonatal Deaths**

**Neonatal deaths must be reported to the Coroner in the first instance.**

A post mortem will be offered to all parents following a pregnancy loss at 12/40 weeks or later. The doctor caring for the mother of a pregnancy loss over 12/40 weeks will advise the parents regarding consideration of a Hospital post mortem examination. Staff will sensitively determine if the parents are willing to discuss consent and will offer them the SANDS booklet "Deciding about a post mortem examination". They will discuss with the parents the merits of a post mortem and how that may be of benefit, for example planning future pregnancies. The parents will be informed how and when the post mortem results should be available.

These cases are referred to a specialist centre through the Bristol Perinatal Pathology Network.

The doctor, midwife or bereavement support officer will take consent for these post mortem examinations. Consent will be sought from the mother and where appropriate both parents will be involved. The procedure for Obtaining Consent for a Perinatal Post Mortem is followed. All consent forms will be audited by a Bereavement Support Officer before being sent to Bristol – any errors or omissions will be discussed with the consent taker and/or parents and be corrected before being sent.

The referral to the specialist centre introduces delays as it can take a couple of weeks before the child is returned to North Devon. This will be discussed with the parents during the consent process and the implications of any decisions they may make explained to them. From this they will be able to make an informed choice when giving consent. The Bereavement Support Office will keep the parents up to date with progress and answer any questions they may have throughout the process until the baby has returned from Bristol and been taken into the care of a Funeral Director.

Parents will be given an appointment to discuss the post mortem results with members of the clinical team caring for them. The Bereavement Support Office will monitor the process; there is a robust system in place to ensure parents receive the results as soon as possible after they have been received by their consultant. They will also be offered a written copy of the consultant's letter to the GP detailing the post mortem results.

Where parents decline a post mortem the Bereavement Support Office will confirm the decision with them before funeral arrangements are made to give them an opportunity to change their mind and to ensure they have had all the information required to make an informed decision.

#### **4.8 Foetal Remains up to 23 weeks and 6 days gestation**

If clinically appropriate, foetal remains are sent for histological examination. Foetal remains include ectopic pregnancies, miscarriages and early intrauterine deaths. The Histopathology department takes a representative sample for histological examination. If foetal remains are identified by eye they are NOT submitted for

histological examination. Arrangements are made for the sensitive disposal of residual material and if any foetal remains are identified in the histology through examination under a microscope the sampled material it is also included for sensitive disposal.

The tissue taken for histological examination, as long as no foetal remains are identified under a microscope tissue is retained in the histopathology department as part of the medical record, for the retention periods set out above for tissue from the living. If requested the Histopathology department will arrange for the examined tissue to be sensitively disposed of as well.

#### **4.9 Funeral Arrangements/Sensitive Disposal**

The wishes of parents are central to this and we provide information to women and couples in the form of information leaflets and through the Bereavement Support Office and electronically on our website about the choices available to them.

Personal, religious or cultural needs relating to the disposal of the pregnancy remains are met wherever possible.

#### **4.10 Funeral arrangements for Foetal Remains up to 23 weeks and 6 days gestation**

- If the parents choose not to be involved, arrangements are made with their permission for a shared cremation with other foetal remains at North Devon Crematorium, Barnstaple and burial of ashes in the children's area of the crematorium garden of remembrance. Please be aware that it may not be possible to recover ashes and it is not possible to recover individual ashes from a shared cremation. Parents are given a choice of a Christian service or a non-religious committal. Arrangements can be made to meet personal, cultural or religious needs where the shared cremation is not appropriate.
- If parents request to attend the shared cremation they will sensitively be offered the choice of an individual funeral arranged either by themselves or the hospital.
- Home burial is a choice and we support parents considering this by providing them with the required information to determine if it is a viable option for them. If they decide to go ahead the Bereavement Support Office will support the parents with advice and arrangements.
- In all circumstances if the parents wish to be involved the Bereavement Support Office will arrange an individual cremation or burial which they can attend, involving the parents as much as they wish.
- The parents can make suitable private arrangements with their chosen funeral director and the Bereavement Support Office will support them in doing this.
- Arrangements can be made to meet personal, cultural or religious needs.

#### **4.11 Funeral Arrangements for Stillbirths and Neonatal Deaths**

- In all circumstances if the parents wish to be involved the Bereavement Support Office will arrange an individual cremation or burial which they can attend, involving the parents as much as they wish.
- Home burial is a choice and we support parents considering this by providing them with the required information to determine if it is a viable option for them. If they decide to go ahead the Bereavement Support Office will support the parents with advice and arrangements.

- The parents can make suitable private arrangements with their chosen funeral director and the Bereavement Support Office will support them in doing this.
- Arrangements can be made to meet personal, cultural or religious needs.

#### 4.12 Sensitive Disposal Following a Termination of Pregnancy

Arrangements are made for a shared cremation with other foetal remains at North Devon Crematorium, Barnstaple and burial of **ashes** in the children's area of the crematorium garden of remembrance. Please be aware that it may not be possible to recover ashes and it is not possible to recover individual ashes from a shared cremation. An individual cremation or burial can be arranged upon request to meet personal, religious or cultural needs.

#### 4.13 Existing Holdings

Northern Devon Healthcare Trust holds identifiable existing holdings and records for tissue blocks and slides from the deceased taken during the course of post mortem examinations at North Devon District Hospital.

They are held for 30 years as part of the medical record, may be used for quality assurance and training and then clinically disposed of. It is lawful to store and use for scheduled purposes, without consent, existing holdings. All tissue samples are anonymised if used for these purposes. If the views of a deceased person or their relatives and friends are known these views are respected and the tissue is not used.

Northern Devon Healthcare Trust deals with enquiries about retained tissue in a timely manner, open and honestly. It will make reasonable arrangements for disposal, if requested in accordance with the wishes of relatives.

If the wishes of relatives are known in regard to storage and disposal of existing holdings Northern Devon Healthcare Trust complies with them.

Where relatives have contacted Northern Devon Healthcare Trust about existing holdings but not requested disposal they will be stored until the relatives make their wishes clear.

Existing holdings about which no contact has been made by the relatives will be retained. Relatives will not be contacted to make enquiries about the future storage and disposal of existing holdings.

#### 4.14 Tissue Obtained During the Course of Medical Treatment

Although consent to treatment and examination is covered by common law and the Mental Capacity Act (2005), please refer to the Trust's Consent policy, consent for scheduled purposes is covered by the Human Tissue Act. Thus it is important that those seeking consent for treatment can inform patients of the content of this policy and answer any questions they may have.

Northern Devon Healthcare Trust retains and stores tissue obtained during the course of medical treatment following the Guidance issued by the Royal College of Pathologists and the Institute of Biomedical Science.

- Surgical specimens (wet tissue specimens) are retained for 4 weeks after the final report.
- Tissue blocks and slides are kept as a permanent part of a patient's medical record for 30 years.
- All tissue is labeled with unique laboratory identification numbers and accurate records are kept of the tissue held to ensure traceability. It is stored in facilities that help maintain the integrity of the tissue for the duration of the retention period.
- Tissue is disposed of by incineration as clinical waste after the retention periods.

Patients can make their own arrangements for disposal as long as the proposed method is lawful, but they will have to incur the costs. It is the responsibility of the person taking consent to inform the Histopathology laboratory to ensure the correct arrangements are made. The Histopathology laboratory will be responsible for facilitating this, indicating to those receiving the tissue the hazards associated with it.

Once tissue has been taken from the living it can be stored and used for a number of purposes without consent under the Human Tissue Act:

- Clinical Audit
- Education and training relating to human health
- Performance assessment
- Public health monitoring
- Quality assurance/ Control material

Northern Devon Healthcare Trust uses suitable tissue obtained during the course of medical treatment for these purposes. This is essential to ensure the high quality of service which all patients have the right to expect. All tissue samples are anonymised if used for these purposes.

If the person consenting for medical treatment wishes to opt out of having their tissue used for these purposes this will be respected. The person taking consent must ensure this is documented and inform the Histopathology department.

Under the Human Tissue Act, consent is required for the storage and use of tissue for:

- Obtaining scientific or medical information which may be relevant to any person including a future person.
- Public Display.
- Research in connection with disorders, or the functioning, of the human body. Tissue from the living may be used without consent provided that the person from whom that material has come remains anonymous to the researcher.
- Transplantation.

Northern Devon Healthcare Trust only allows tissue to be used for obtaining medical information which may be relevant to any other person if consent is given by the patient; or if the patient cannot give consent by someone in a qualifying relationship.

Northern Devon Healthcare Trust does allow tissue to be used anonymously in appropriately approved research.

The pathology department will ensure consent has been given for these purposes before releasing tissue.

Tissue from the living will continue to be treated as such after a patient has died as it is the time the tissue is taken that determines how it is affected by the Human Tissue Act 2004.

## **5. Monitoring Compliance with and the Effectiveness of the Policy**

### **5.1 Standards / Key Performance Indicators**

Key performance indicators comprise:

- Audit of post mortem tissue held in the pathology department.
- Review of the consent for post mortem examinations.
- Audit of practice against the latest national standards and guidance for the work covered by this policy.

### **5.2 Process for Implementation and Monitoring Compliance and Effectiveness**

#### **Process for Implementation**

All post mortem consent forms will be checked by the bereavement support office before any post mortem takes place. Tissue retained from post mortem examinations will be audited regularly to ensure it is being retained or disposed of in accordance with the appropriate consent.

#### **Monitoring Compliance and Effectiveness**

This policy will be monitored to ensure it conforms to the latest guidelines and good practice for performing post mortem examinations and the retention and disposal of human tissue obtained during the course of medical treatment and post mortem examinations.

This policy will be subject to audit through the department of pathology quality management system.

Monitoring compliance with this policy will be the responsibility of the Designated Individual named on Northern Devon Healthcare Trust Human Tissue Authority licence.

Where non-compliance is identified, support, advice and training to improve practice will be given by the Pathology Service Manager (DI) or an appropriate person identified by the DI.

## 6. Equality Impact Assessment

**Table 1: Equality impact Assessment**

Group	Positive Impact	Negative Impact	No Impact	Comment
Age			X	
Disability			X	
Gender			X	
Gender Reassignment			X	
Human Rights (rights to privacy, dignity, liberty and non-degrading treatment), marriage and civil partnership			X	
Pregnancy	X			
Maternity and Breastfeeding				
Race (ethnic origin)			X	
Religion (or belief)	X			Different cultures and religions have different opinions about the acceptability of post mortem examinations and tissue retention. This policy sets out to treat everyone as individuals and allow for decisions to be made on that basis regardless of religion or belief. It does, where the law permits, allow religion or belief to inform the choices individuals make.
Sexual Orientation			X	

## 7. References

- Human Tissue Act, 2004
- [Human Tissue Authority Code of Practice – Post Mortem Examination](#)
- [Human Tissue Authority Code of Practice – Consent](#)
- [Human Tissue Authority Code of Practice – Disposal of Relevant Material](#)
- [Human Tissue Authority - Guidance on the disposal of pregnancy remains following pregnancy loss or termination](#)

- [The retention and storage of Pathological records and archives \(5<sup>th</sup> edition, 2015\). Guidance from the Royal College of Pathologists and the Institute of Biomedical Science](#)
- [Managing the Disposal of Pregnancy Remains 2018 – Royal College of Nursing](#)
- [Working Together to Safeguard Children \(WTtSC\). A guide to inter-agency working to safeguard and promote the welfare of children, July 2018.   
<https://www.gov.uk/government/publications/working-together-to-safeguard-children--2>](#)

## 8. Associated Documentation

- Information for consent takers: Local practices and arrangements
- [Consent Policy](#)
- Obtaining Consent for Hospital Adult Post Mortems SOP– Available from the bereavement office
- Obtaining Consent for a Perinatal Post Mortem SOP– Available from the bereavement office
- [Interpretation and Translation Policy](#)
- [Last Offices - Standard Operating Procedure \(& Care After Death following a death in Hospital \)SOP No. 09/060](#)
- Post mortem consent form for an adult – Available from the bereavement office
- [A guide to the hospital PM on an adult](#)
- Request form for a Hospital PM – Available from the bereavement office
- Post mortem consent form for a baby/child – Available from the bereavement office
- [Understanding Why Your Baby Died \(and Post Mortem\) – Information for Parents \(SANDS\)](#)
- Bristol Perinatal Pathology Network – Perinatal post mortem request form
- Protocol for Peninsula Child Death Overview (July 2014) or revision
- [Information for parents following the loss of a new born baby \(Patient Information Leaflet 535\)](#)
- [Information for parents following a Stillbirth \(Patient Information Leaflet 533\)](#)
- [Information for parents following a Miscarriage \(Patient Information Leaflets 734 and 735\)](#)
- Foetal Remains Flow Chart – Available in pregnancy loss box file\*
- Stillbirth Flow Chart– Available in pregnancy loss box file\*

- Neonatal Death Flow Chart– Available in pregnancy loss box file\*

*\*The pregnancy loss box files are available in relevant clinical areas and contain the guidance, patient information leaflets and forms needed following a pregnancy loss. The bereavement support office manages and updates their content as required.*