Consent Policy for Removal, Storage and Use of Human Organs and Tissue for Scheduled Purposes including Post Mortem

<table>
<thead>
<tr>
<th>Document Author</th>
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<tr>
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<td><strong>Authorised by:</strong> Chief Executive</td>
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<td><strong>Date:</strong> November 2016</td>
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<td><strong>Policy Lead Director:</strong> Chief Executive</td>
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DOCUMENT HISTORY

(Procedural document version numbering convention will follow the following format. Whole numbers for approved versions, e.g. 1.0, 2.0, 3.0 etc. With decimals being used to represent the current working draft version, e.g. 1.1, 1.2, 1.3, 1.4 etc. For example, when writing a procedural document for the first time – the initial draft will be version 0.1)

<table>
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<tr>
<th>Date of Issue</th>
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<td>Chief Executive</td>
<td>Formatting updated</td>
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<td>5th November 2013</td>
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<td>Approved at Clinical Services Group</td>
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<td>Chief Executive</td>
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<td>Chief Executive</td>
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<td>2.2</td>
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<td>Chief Executive</td>
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<td>Corporate Governance &amp; Risk Sub Committee</td>
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<td>13th December 2016</td>
<td></td>
<td></td>
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<td>For Approval</td>
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NB This policy relates to the Isle of Wight NHS Trust hereafter referred to as the Trust.

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B. Who are the Nominated Representatives

C. Licensing and Consent Flowcharts

D. Financial and Resourcing Impact Assessment on Policy Implementation

E. Equality Impact Assessment Screening Tool
1. EXECUTIVE SUMMARY

The Human Tissue Act 2004 (HT Act) provides a framework for regulating the removal, storage and use of human organ and other tissues for scheduled purposes:

Schedule 1 consists of 2 parts, namely:

Part 1 – purposes requiring consent: living and deceased persons:

(a) anatomical examination;
(b) determining the cause of death;
(c) establishing after a person’s death the efficacy of any drugs or other treatment administered to him;
(d) obtaining scientific or medical information about a living or deceased person which may be relevant to any other person (including a future person);
(e) public display;
(f) research in connection with disorders, or the functioning, of the human body;
(g) transplantation.

Part 2 – purposes requiring consent: deceased persons:

(h) clinical audit;
(i) education or training relating to human health;
(j) performance assessment;
(k) public health monitoring;
(l) quality assurance.

The HT Act established the Human Tissue Authority (HTA) to regulate activities concerning the removal, storage, use and disposal of human tissue. The HTA is also a Competent Authority for the Human Tissue (Quality and Safety for Human Applications) Regulation 2007.

In broad terms, the HT Act and the HTA's codes of practice require that consent is required to:

1. store and use dead bodies;
2. remove, store and use relevant material from a dead body;
3. store and use relevant material from the living.

Anyone removing, storing or using material in circumstances for which the HT Act requires consent must be satisfied that consent is in place.

Consent to treatment and examination is covered by the common law and the Mental Capacity Act (MC Act) 2005 (www.legislation.gov.uk/ukpga/2005/9/contents) where appropriate.

Trusts policies are in place for obtaining consent to treatment and the legal position is set out in the Department of Health's guidance:
See also the GMC guidance on consent and decision making in Consent: patients and doctors making decisions together:

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2. INTRODUCTION

The HTA codes of practice on consent are based on some key principles:

- as a first step, a willingness to discuss the question of consent should be established
- full information about the consent process, should be available in widely spoken languages and in a variety of formats, and in line with other legislation, such as the Disability Discrimination Act 1995 [www.legislation.gov.uk/ukpga/1995/50/contents]. Consent should be based on an understanding of what the procedure involves; this applies to those seeking consent, as well as to those giving it.

**Appropriate consent** is defined in terms of the person who may give consent.

For consent to be valid it must be given voluntarily, by an appropriately informed person who has the capacity to agree to the activity in question. The HTA code of practice sets out guidance for practitioner on how to make appropriate consent valid: https://www.hta.gov.uk/guidance-professionals/codes-practice/code-practice-1-consent?faArea1=customwidgets.content_view_1&cit_id=779&cit_parent_cit_id=652

All consent must be valid in the context of the HT Act. It is important to respect the consent given, regardless of its scope or duration.

3. SCOPE

In accordance with the HT Act this policy applies to the removal, storage and use of human organ and other tissues for scheduled purposes from individuals. This policy does not apply to deceased patients for whom the Coroner investigates the death as consent for removal and storage of tissue is not required for Coronial or criminal justice purposes.

This policy relates to both clinical and administrative staff involved in the consent process.

4. PURPOSE

This policy sets out the process for obtaining valid and informed consent for the removal, storage and use of human organ and other tissues for scheduled purposes (Schedule 1) within the Isle of Wight NHS Trust.

5. ROLES AND RESPONSIBILITIES

5.1 The HTA Licence Holder (Executive Medical Director) has a key role along with the Designated Individuals (see below)

The role of Licence Holder does not impose the duties that are expected of the DI; however, it is important to note that they have the right to apply to the HTA to vary the licence. This enables them to substitute another person as the DI and allows the establishment to cover circumstances where the DI is unable to oversee the licensable activity(s). Consequently, the HTA prefers individual licence holders to be more senior than the DI (i.e. Medical Director / Chief Executive).

The HTA is required to provide all notices of licence decisions to both the LH and the DI.
5.2 **The consultant or senior doctors** requesting consent from the person in qualifying relationship must be well informed and appropriately trained in seeking consent with a thorough knowledge, and purpose, of the procedures will be undertaken.

5.3 **The Designated Individuals (DI)** 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 (*Section 18*) is authorised to be undertaken. They have the primary (legal) responsibility under *Section 18* of the HT Act to secure:

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

Any enquiries regarding practices that are under the remit of HT Act and HTA should be directed to the DI and HTA. Currently the DI role is held by the Consultant Histopathologist.

5.4 **All staff** who are involved in obtaining consent for the removal, storage and use of human organ and other tissues for scheduled purposes have a duty to follow this policy in line with the HT Act.

5.5 **Responsibility of Health Professionals**

It is a health professional’s own responsibility:

- to ensure that when they require colleagues to seek consent on their behalf they are confident that the colleague is competent to do so; and
- to work within their own competence and not to agree to perform tasks which exceed that competence.

6. **POLICY DETAIL / COURSE OF ACTION**

The following contains the necessary requirements that are required to comply with the Human Tissue Act 2004.

7. **SCOPE OF CONSENT**

Consent may differ in its scope as it may be generic or specific.

Generic consent typically only applies to research. If conducting research on samples of tissue, it is good practice to request generic consent because this avoids the need to obtain further consent in the future. It is still important however that the consent is valid (see the HTA code of practice on Research for further guidance).

8. **DURATION OF CONSENT**

Consent may differ its duration. It may be enduring of time-limited.

Ensuring consent means that it remains in force unless consent is withdrawn. A person may, however, specify a time limit for how long they wish their consent to remain in force. In both cases, the decision should be clearly documented in the patient's records, the laboratory records or both.

9. **WITHDRAWAL OF CONSENT**

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Consent may be withdrawn at any time whether it is generic or specific. Withdrawal should be discussed at the outset when consent is being sought. The practicalities of withdrawing consent and the implications of doing so should be made clear, for example, for potential recipients if the donated tissue is for clinical use. Withdrawal of consent cannot be effective where tissue has already been used.

If someone withdraws consent for samples to be used in any future projects, this does not mean that information and research data should be withdrawn from any existing projects.

A person's agreement or refusal to consent to the removal, storage or use of tissue for purposes under the HT Act must not affect the investigation or treatment that they receive.

10. CONSENT REQUIREMENTS

10.1 General provisions

Before deciding whether to proceed with the removal, storage or use of tissue for scheduled purposes, the following should be considered:

1. Does the activity require consent?
2. Who may give consent?
3. Has sufficient written or verbal information been provided for the person giving consent to make a properly considered decision?
4. How will the consent be given and recorded?
5. When is written consent required?
6. Is consent needed for more than one purpose?
7. If a child is involved, are they competent to consent and have they expressed particular wishes or views?
8. If an adult lacks capacity to consent, how should the provisions of the MC Act be applied?
9. What are the exceptions to the consent provisions of the HT Act?
10. Is DNA analysis likely to be involved?
11. What are the consent implications for foetal tissue?

10.1.1 When to seek consent

Where possible, it is good practice to seek the person's consent to the proposed procedure in advance. Sufficient time should be allowed for questions and discussion.

Equally, discussions with families may often take place in hospital before a person's death. They may know the person's wishes in respect of, for example, donating organs for transplantation. It should be made clear to them, however, that knowing and understanding the dying person's wishes is different from consenting on their behalf following their death.

The seeking and obtaining of consent from patients before death or from those close to them after their death requires sensitivity. This is especially true for donations for transplantation, post-mortem examinations and the retention of tissue and organs for research. Further guidance is set out in HTA codes of practice on Post-mortem examination and Donation of solid organs for transplantation.

10.1.2 When do you need consent?

Tables 1 & 2 identify when consent is required as per the HT Act and when it is recommended best practice:
Table 1
Table setting out consent requirements under the HT Act for scheduled purposes.

<table>
<thead>
<tr>
<th>Scheduled purpose</th>
<th>Consent required for human tissue from the living</th>
<th>Consent required for human tissue from the deceased</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Removal</td>
<td>Storage</td>
</tr>
<tr>
<td>Anatomical examination</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>Determining the cause of death**</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>Establishing after a person's death the efficacy of any drug or other treatment administered to them</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>Obtaining scientific or medical information about a living or deceased person which may be relevant to any person (including a future person)</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>Public display</td>
<td>X*</td>
<td>✓</td>
</tr>
<tr>
<td>Research in connection with disorders, or the functioning of the human body</td>
<td>X*</td>
<td>✓</td>
</tr>
<tr>
<td>Transplantation</td>
<td>X*</td>
<td>✓</td>
</tr>
<tr>
<td>Clinical audit</td>
<td>X*</td>
<td>X</td>
</tr>
<tr>
<td>Education or training</td>
<td>X*</td>
<td>X</td>
</tr>
<tr>
<td>Performance assessment</td>
<td>X*</td>
<td>X</td>
</tr>
<tr>
<td>Public health monitoring</td>
<td>X*</td>
<td>X</td>
</tr>
<tr>
<td>Quality assurance</td>
<td>X*</td>
<td>X</td>
</tr>
</tbody>
</table>

✓ Consent is required under the HT Act
X Consent is not required under the HT Act
* Consent is required under the common law of removal of tissue from the living
** Consent is not needed for investigating cause of death under the authority of the coroner

(taken from: http://www.hta.gov.uk/legislationpoliciesandcodesofpractice/codesofpractice/code1consent.cfm?faArea1=customwidgets.content_view_1&cit_id=778&cit_parent_cit_id=652)
### Table 2

Table setting out when consent is required for different activities and when it is recommended as good practice.

<table>
<thead>
<tr>
<th>Activity</th>
<th>Consent required</th>
<th>Consent recommended as good practice</th>
<th>Guidance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Storage and/or use of tissue from the living for the scheduled purposes:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>I. obtaining scientific or medical information which may be relevant to any other person, now or in the future</td>
<td>✓</td>
<td>Paragraph 113</td>
<td></td>
</tr>
<tr>
<td>II. public display</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>III. research</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>IV. transplantation</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Storage and/or use of tissue from the living for research, where the research is ethically approved and the tissue is non-identifiable</td>
<td>X</td>
<td>Paragraph 117 - 123</td>
<td></td>
</tr>
<tr>
<td>Storage and/or use of tissue from the living for the scheduled purposes of:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>I. clinical audit</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>II. Education or training relating to human health</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>III. performance assessment</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>IV. Public health monitoring</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>V. quality assurance</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Diagnosis and treatment</td>
<td>X</td>
<td>Consent is required under the common law for removal of tissue from the living.</td>
<td>Paragraph 115 - 116</td>
</tr>
</tbody>
</table>

(taken from: [http://www.hta.gov.uk/legislationpoliciesandcodesofpractice/codesofpractice/code1consent.cfm?faArea1=customwidgets.content_view_1&cit_id=778&cit_parent_cit_id=652](http://www.hta.gov.uk/legislationpoliciesandcodesofpractice/codesofpractice/code1consent.cfm?faArea1=customwidgets.content_view_1&cit_id=778&cit_parent_cit_id=652))

#### 10.1.3 Who may seek consent?

It is usually the responsibility of the healthcare professional to seek consent from the person concerned, the person with parental responsibility, or a partner, relative or close friend (see appendix A for hierarchy of qualifying relationships), though seeking consent may be assigned to someone else, as long as they are appropriately trained to ensure the consent is valid.

#### 10.1.4 Format of consent

Written consent is required and consent forms such as the Hospital post mortem consent form for adult and children are available to use. These are available on the intranet at [http://intranet.iow.nhs.uk/Clinical-Risk](http://intranet.iow.nhs.uk/Clinical-Risk).

Written, witnessed consent is always needed for anatomical examination and for public display of dead bodies or body parts (see HTA codes of practice on [Anatomical examination](http://www.hta.gov.uk/legislationpoliciesandcodesofpractice/codesofpractice/code1consent.cfm?faArea1=customwidgets.content_view_1&cit_id=778&cit_parent_cit_id=652) and [Public display](http://www.hta.gov.uk/legislationpoliciesandcodesofpractice/codesofpractice/code1consent.cfm?faArea1=customwidgets.content_view_1&cit_id=778&cit_parent_cit_id=652) for detailed guidance).

Written consent should be obtained wherever possible for all post mortem activities.
If verbal consent is obtained, this should be clearly documented in the patient's records, the laboratory records or both. The record should detail when consent was obtained and the purpose for which the consent was given.

10.1.5 Religion, belief and culture

Attitudes towards the use of tissue and especially towards post mortems may vary widely among cultures and religions. All healthcare professionals should be sensitive to this.

10.1.6 Communication

Consent is valid only if proper communication has taken place. Particular consideration should be given to the needs of individuals and families whose first language is not English. Any difficulties in communicating with the person interviewed (e.g. because of language, literacy or hearing difficulties), and an explanation of how these difficulties were overcome (e.g. through an independent translator), should be recorded.


The following specific provisions, in accordance with the Disability Discrimination Act 2004 are made for those patients who, for reasons of disability or otherwise, would not find printed information particularly assessable:

- **Blind**  The Isle of Wight Blind Society have produced an audio cassette of the ‘About the Consent Form’ leaflet and can put other leaflets onto tape as required, and can also assist with providing information in large print and Braille

- **Deaf**  The Hampshire Interpreting Service provide an interpreting service for people with deafness or reduced hearing

For further advice and support on how to access information in alternative formats please use the link below:

http://intranet.iow.nhs.uk/Interpreting-and-Translation-Services

10.1.7 Provision for patients whose first language is not English

The Isle of Wight NHS Trust is committed to ensuring that patients whose first language is not English receive the information they need and are able to communicate appropriately with healthcare staff. It is not appropriate to use children to interpret for family members who do not speak English.

Staff can contact the National Interpreter Service by telephoning 0800 028 0073 and using the client Identification number 269053 or by contacting the Corporate Governance & Risk Management Department.

10.2 Tissue from the deceased

10.2.1 When is consent required?

Under the HT Act, consent is needed for the removal, storage and use of material from the deceased for all scheduled purposes. Please see tables 1 & 2.

Where an adult has, whilst alive, given valid consent for any particular donation or the removal, storage or use of their body or tissue for scheduled purposes

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If those close to the deceased person object to the donation, for whatever purpose, when the deceased person (or their nominated representative – see appendix A) has explicitly consented, healthcare professionals should seek to discuss the matter openly and sensitively with them. They should be encouraged to accept the deceased person’s wishes and it should be made clear that they do not have the legal right to veto or overrule those wishes (see HTA code of practice on Donation of solid organs for transplantation).

10.2.2 Providing information about the consent process

When seeking consent from a nominated representative or from a person in a qualifying relationship, full and clear information should be provided about the purpose for which consent is being sought. This should allow them to make a properly considered decision. This information should include the nature of the intended activities and the reasons for them. More information on nominated representatives and qualifying relationships can be found by visiting: http://www.hta.gov.uk/legislationpoliciesandcodesofpractice/codesofpractice/code1consent.cfm?faArea1=customwidgets.content_view_1&cit_id=666&cit_parent_cit_id=652

An information leaflet is available regarding Post Mortem and is available on the intranet http://nww.iow.nhs.uk/guidelines/Relatives_Information_for_Post_Mortem_Examination-v2.pdf

10.2.3 Disclosing information about the deceased

Care should be taken regarding the possible disclosure of information, such as genetic information or HIV status, which the deceased person may not have wished to be disclosed, or which may have significant implications for other family members.

In making decisions, healthcare professionals will have to have regard to their duty of patient confidentiality and ensure they consider the provisions of the Data Protection Act 1998 www.legislation.gov.uk/ukpga/1998/29/contents. In certain circumstances, it may be necessary to share sensitive information with the family if the results of the activity have the potential to affect them or other relatives. For further guidance see GMC guidance on confidentiality www.gmc-uk.org/guidance/ethical_guidance/confidentiality.asp and the Department of Health’s guidance on confidentiality www.gov.uk/government/publications/confidentiality-nhs-code-of-practice which deals with disclosing information after a patient has died.

10.2.4 Seeking consent for multiple activities

When someone has died, healthcare professionals may wish to seek consent for more than one scheduled purpose. In this case, it would be appropriate to seek the relevant consent for the activities but should ideally be sought in a single consent process and recorded in the same place. Anticipating and explaining the purpose for which tissue could be used will avoid the need for seeking consent on repeated occasions.

10.2.5 Exceptions for coroners and criminal justice purposes

For tissue from the deceased, consent is not needed for:

1. carrying out an investigation into the cause of death under the authority of a coroner
2. Retention of material after a post mortem under the authority of a coroner, for a period no longer than the time needed by the coroner to discharge their statutory functions, if certified in writing with an explanation by the pathologist that it bears on evidence concerning the cause of death. See Coroners Rules for further detail.

However, consent is required for research or other scheduled purposes where the coroner's authority to retain the material has ended and the deceased's family have not opted to dispose of the material. This applies to all tissue removed at post mortem, including small samples such as blocks and slides, and samples that might include relevant material such as toxicology and microbiology specimens.


10.3 Tissue from the living

10.3.1 When is consent required?

Under the HT Act, consent from the living is needed for storage and use of tissue as per table 1 above.

Although consent for treatment and examination is dealt with under the common law and consent for scheduled purposes is dealt with under the HT Act, the consent for each activity may be obtained at the same time. It is still important to explain clearly the activity for which consent is being obtained, including the risks and wider implications. Further guidance on this issue in respect of obtaining consent for donation may be found in HTA code of practice on Donation of solid organs for transplantation.

10.3.2 Consent exception for research in specific circumstance

The flow charts found in Appendix B & C provide information relating to licensing and consent requirements for human tissue for research from the living and the ethical approval process.


10.3.3 Powers deeming consent to be in place

Section 7 of the HT Act allows the HTA to dispense with the need for consent in certain circumstances.

The HTA has the power to deem consent to be in place for relevant material from someone who is untraceable, or who has not responded to requests for consent to use of their material, if that material could be used to provide information relevant to another person. This may be important where information could be obtained about the treatment and diagnosis of the applicant. The HTA has prepared guidance on the implementation of these provisions in relation to DNA analysis.

10.3.4 Consent and the use of DNA

Qualifying consent is required to analyse DNA, subject to certain exceptions. This means that if consent to use material has been obtained under the HT Act for a scheduled purpose, it is not necessary to obtain separate consent where that use also includes post mortem
involves DNA analysis, but that it should be made clear to the donor that their bodily material may be used for this purpose, if that is the intention. When discussing consent, the donor should be made aware if the intended DNA analysis may reveal significant results e.g. a family genetic condition. Their decision on whether they wish such information to be made known to them should be respected in appropriate cases.

For more information about issues of consent and confidentiality in clinical practice in the genetics service, see the report of the Joint Committee on Medical Genetics, Consent and confidentiality in genetic practice: Guidance on genetic testing and sharing genetic information
http://www.clinmed.rcpjournal.org/content/12/1/5.full?related-urls=yes&legid=clinmedicine;12/1/5 and Research and the Human Tissue Act - DNA Analysis
www.mrc.ac.uk/research/facilities-and-resources-for-researchers/regulatory-support-centre/human-tissue/

Further information can be found by visiting www.hta.gov.uk/policies/non-consensual-dna-analysis

10.3.5 Foetal tissue
This section covers the disposal of 'foetal tissue' resulting from a number of different pregnancy losses, including ectopic pregnancies, miscarriages, early intrauterine foetal deaths and termination of pregnancy.

The law does not distinguish between foetal tissue and other tissue from the living; foetal tissue is regarded as the mother’s tissue. Consequently, foetal tissue is subject to the same consent requirements under the HT Act as all other tissue from the living. However, because of the sensitivity attached to this subject, it is good practice to always obtain consent for the examination of foetal tissue and for its storage or use for all scheduled purposes.

It is also good practice to obtain consent for research on non-foetal products of conception (i.e. placenta, membranes, umbilical cord, amniotic fluid), even where the tissue is non-identifiable. Consent for removal and disposal of any tissue within the Trust is included in the consent for the operation/procedure.

It should be noted that the reference to foetal tissue here does not include stillbirths (babies born dead after 24 weeks gestation), or neonatal deaths (babies or foetuses of any gestational age which are born showing signs of life and die before the age of 28 days). Obtaining consent for the removal, storage or use of the tissue of babies from stillbirths or neonatal deaths should be handled in accordance with provisions for gaining consent for use of the tissue of the deceased. It is recommended that, whenever possible, the consent process for the examination of stillbirths and neonatal deaths involves the mother, and that, where appropriate, both parents are involved.

Further information can be found at:

Although national guidance is available in the code of practice on Disposal of human tissue local arrangements for disposal following pregnancy loss is as follows:

For all pregnancy loss delivered before 13 weeks (Including medical management of missed miscarriage, planned or social termination of pregnancy up to 12 weeks and 6 days and ectopic pregnancy
• All foetal tissue taken as part of any surgical procedure is sent to histology to confirm that no foetal tissue has been retained. This material is individually bagged and then amalgamated and disposed of by means of a joint burial at the ‘Born to Soon’ service at the Crematorium. These services take place 3 – 4 times a year (February, June and October) with foetal tissue being retained until the next available service.

All planned or social termination of pregnancy over 12 weeks and 6 days

• All patients are transferred to the British Pregnancy Advisory Service (BPAS) who undertake the procedure off Island. Issues concerning the disposal of any foetal tissue are therefore under the remit of the BPAS.

All pregnancy loss delivered after 13 weeks up to 24 weeks, are managed through the Maternity Unit

• All foetal tissue from patients who deliver in the Maternity Unit is disposed of individually either by;
  • a joint burial, ‘Born to Soon’ service at the Crematorium; or
  • parents can make their own arrangements for a separate burial.

Pregnancy loss at >24 week

• All foetal tissue from patients who deliver in the Maternity Unit are offered a burial at the Children’s garden at the Crematorium, the basic costs of which are supported by the Trust.

11. CONSENT FOR POST MORTEM EXAMINATIONS CARRIED OUT UNDER THE AUTHORITY OF THE CORONER

Consent is not required for PM examinations or the storage of material retained during PM examinations, where there is authorisation from a coroner; however, consent is required for the continued storage or use of tissue once the coroner’s purposes are complete.

In cases of perceived problems with hospital care or prison deaths an independent Post Mortem is undertaken by either a Consultant Histopathologist from another hospital (usually Winchester) or a Home Office Pathologist. Copies of medical records are usually requested to aid this examination.

12. CONSENT FOR A HOSPITAL POST MORTEM EXAMINATIONS

A requested hospital post mortem examination is carried out to further understand the deceased patient’s disease processes and effectiveness of any treatments the patient may have received, histological studies of diseases, audit and accurate mortality and morbidity studies, and teaching and training of medical students, doctors or other health care professional.

A Medical Certificate for the Cause of Death (MCCD) must be issued before requesting a post mortem.

Those who obtain consent for PM examinations have to ‘reasonably believe’ that an appropriate individual has given consent so that no offence will be committed under section 5 of the HT Act.

Before the discussion with relatives, the responsible clinician should consider obtaining advice from a pathologist on which, if any, tissue is likely to be retained, for how long and for what
purpose. Thereafter, the pathologist undertaking the PM examination should be available for a
discussion with the deceased person’s relatives if they wish.

Consent must be from, in order, the person in life, their nominated representative, or, in the
absence of either of these, someone in a *qualifying relationship* with them immediately before
they died - in which case a hierarchy applies (HTA Act section 27(4)).

The named next of kin may not be the person in the highest ranking *qualifying relationship* under
the HT Act. Hospital staff should take the opportunity, when seeking consent for a hospital PM
examination process, to explain the significance of the qualifying relationship under the HT Act to
the next of kin. They should then ask the next of kin if they are the person in the highest ranking
qualifying relationship. If they are not, information should be requested about who is the highest
ranking person and reasonable efforts made to contact the person prior to the PM examination
taking place. This information should be documented on the consent form.

There may be situations where it may not be possible to seek consent from the person in the
highest ranking qualifying relationship. The HT Act allows for this person to be omitted from the
hierarchy if they cannot be located, declines to deal with the matter or is unable to give valid
consent; for example, because they are a child or lack capacity to consent. In such cases, the
next person in the hierarchy would become the appropriate person to give consent. This process
should be documented on the consent form.

Where consent from a person in a qualifying relationship cannot be obtained, the PM examination
cannot proceed.

Relatives or partners of the deceased can also request that the hospital carry out a post-mortem
to learn more about why their partner or relative died.

**13. CONSENT FOR ANATOMICAL EXAMINATIONS**

Anatomical examination is used to teach healthcare professionals about the structure of the
human body and how it works. Human bodies and parts of bodies are used to train both students
and surgeons.

The Isle of Wight NHS Trust does not hold a license for anatomical examination. Please refer to
the HTA’s list of licensed establishment [www.hta.gov.uk/establishments](http://www.hta.gov.uk/establishments).

**14. TRANSPLANT**


The [code of practice on Consent](http://www.hta.gov.uk/guidance-professionals/codes-practice/code-practice-2-donation-solid-organs-transplantation?FaArea1=customwidgets.content_view_1&cit_id=674&cit_parent_cit_id=669) sets out guiding principles on how the law should be applied to consent for removal, storage and / or use of tissue, including organs, from the body of a deceased person. It should be consulted and read in conjunction with HTA code of practice on donation of solid organ for transplant:

The procurement of tissue for human application is governed by the requirements of the Quality &
Standards (Q&S) Regulations. Procurement may only be undertaken under the authority of a
licence from the HTA or a third party agreement instigated by a licensed establishment. Under the
Q&S Regulations, it is an offence to store tissues or cells for more than 48 hours, including bone
marrow and PBSC for human application, without an HTA licence. It is also an offence to procure,
test, process, distribute, import or export tissues or cells intended for human application without a licence or where appropriate a third party agreement as defined in the Q&S Regulations www.legislation.gov.uk/uksi/2007/1523/contents/made and the HTA’s Directions 002/2007 www.hta.gov.uk/policies/hta-legal-directions

For further detailed guidance on tissue for human application refer to Directions issued by the HTA summarising the requirements of the EUTCD and the Q&S Regulations www.hta.gov.uk/faq/how-was-eu-tissues-and-cells-directive-eutcd-brought-uk-law

14.1 Preservation of organs in cases of uncontrolled non-heart beating donation

As outlined earlier in this code, where donation is a possibility, the deceased’s wishes regarding organ donation should be established as soon as possible. Where the deceased’s wishes are unknown, the views of the relatives on donation should be sought. There may be occasions when steps need to be taken to preserve the viability of an organ, while it is being established if a decision on consent has been, or will be, made.

Preservation of parts of a deceased person’s body for potential use for transplantation is dealt with under Section 43 of the HT Act: www.legislation.gov.uk/ukpga/2004/30/contents

The HT Act makes it lawful to take minimum steps to preserve part of a body for potential transplantation, including in those situations where it is still being established if a decision on consent has been, or will be, made.

In uncontrolled non-heart beating cases, the coroner’s jurisdiction, common law powers and statutory obligations under the 1988 Coroners Act www.legislation.gov.uk/ukpga/1988/13/contents also arise automatically and immediately, and must also be taken into account when any decision regarding taking steps to preserve an organ is required. It should be borne in mind that the parallel powers of the coroner arise when the body is lying in that coroner’s jurisdiction as well as within a hospital, nursing home or other institution.

In all cases, steps should therefore be taken as soon as possible to find out not only the deceased’s wishes on donation, or where these are unknown, the views of the relatives of the deceased, but also whether the local coroner is obliged or otherwise intends to assume jurisdiction to investigate the cause of death.

In cases where the wishes of the deceased regarding consent for organ donation cannot be established, consent should be sought, where possible, from their relatives before the preservation process begins.


Blood and its derivatives used for the purpose of transplantation (including transfusion) are not considered relevant material www.hta.gov.uk/policies/list-materials-considered-be-%E2%80%98relevant-material%E2%80%99-under-human-tissue-act-2004

For the purposes of section 16 of the HT Act and are therefore excepted from the HTA licensing requirements under that section. Additionally, under the Q&S Regulations www.legislation.gov.uk/uksi/2007/1523/contents/made the procurement, processing, preservation, testing, storage, distribution, import or export of blood and blood components for human application are not licensable. However, the procurement, processing, preservation, testing, storage, distribution, import or export of lymphocytes Consent policy for removal, storage and use of human organs and tissue for scheduled purposes including post mortem

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intended for haematopoietic stem cell transplantation are licensable under those Regulations.

For further detailed guidance on tissue for human application refer to Directions issued by the HTA summarising the requirements of the EUTCD and the Q&S Regulations www.hta.gov.uk/faq/how-was-eu-tissues-and-cells-directive-eutcd-brought-uk-law

15. **PUBLIC DISPLAY**

Under the HT Act, public display of the deceased and relevant material from the living or the deceased is a scheduled purpose for which consent is required. In some cases it is also a licensable activity. The difference between scheduled purposes and licensable activities is explained in Appendix A of HTA code of practice on public display (refer item 10.1.2). The Isle of Wight NHS Trust does not hold a license for this sector of the HT Act.

16. **CONSULTATION**

This policy has been through the following consultation process:
- Clinical Standards Group
- Policy Management Committee

17. **TRAINING**

The Consent Policy for removal, Storage and use of Human Organ and Tissue for scheduled purposes (Schedule 1) including Post Mortem has a mandatory training requirement and is reviewed on a yearly basis.
- All doctors requesting consent for removal, storage and use of human organ and tissues should contact the Mortuary, Cellular Pathology Department or Designated Individuals (refer 5.3).
- APT, doctors and midwife can also attend a course organised by The Mortuary Department, HTA and AAPT.

18. **DEFINITIONS**

**Anatomical examination:** Examination by dissection for the purpose of teaching, studying or conducting research into the structure of the human body.

**Best interests:** A test of a person’s best interests takes into account not only the medical but also the wider emotional, psychological and social aspects of the potential procedure, as well as the risks.

**Bodily material:** Defined by the HT Act as material which has come from a human body and consists of, or includes human cells. Unlike relevant material this includes gametes, embryos outside the human body and hair and nail from the body of a living person.

**Cells:** Individual human cells or a collection of human cells when not bound by any form of connective tissue. For establishments licensed for human application this includes cell lines grown outside the human body but not gametes, embryos outside the human body, or blood and blood components.

**Clinical audit:** A process to review explicit criteria and the implementation of change to continuously improve patient care and outcomes.

**Diagnosis:** A process where a disease is identified.
DNA (deoxyribonucleic acid): A polymer made up of a series of repeating units. DNA encodes the instructions required to assemble cells and regulate processes in living cells. The instructions are contained within sections of DNA which are known as genes.

Donation: The act of donating human tissue, cells, organs or part organs for a scheduled purpose either during life or after death.

Donor: Every human source, whether living or deceased, of tissue, cells, organs or part organs.

Existing holdings: The body of a deceased person, or any relevant material which has come from the human body, held immediately prior to 1st September 2006.

Gillick competent (or Fraser competent): In the case of Gillick v West Norfolk and Wisbech Area Health Authority [1986] 1 AC 112 the court found that a child below 16 years of age will be competent to consent to medical treatment if they have sufficient intelligence and understanding to make decisions regarding their own healthcare.

Human application: In relation to tissue or cells, means use on or in a human recipient, including use in applications situated or occurring outside the body, but not including use when tissue and cells are removed from and applied in the same person within the same surgical procedure.

Licensing: A number of activities can only be carried out where the establishment is licensed under the HT Act by the HTA. Organisations whose activities involve the removal, storage or use of relevant material may need to work under an HTA licence. All establishments working under an HTA licence must work to specified standards set by the HTA.

Nominated representative: A person appointed to represent someone after their death who is empowered to consent to the removal, storage and use of the body or tissue for any of the scheduled purposes, other than anatomical examination or public display.

Non-identifiable: Ensuring that if human tissue is removed from a human body, all necessary steps are taken to prevent the person from whose body the material has come from being identified.

Organ: Defined by the HT Act (Persons who Lack Capacity to Consent and Transplants) Regulations 2006. A differentiated and vital part of the human body, formed by different tissues, that maintains its structure, vascularisation and capacity to develop physiological functions with an important level of autonomy.

Parental responsibility: A person who has parental responsibility will usually, but not always, be the child's parent. The category of persons with parental responsibility is as set out in the Children Act 1989.

Part organ: For the purposes of the HT Act and the HT Act (Persons who Lack Capacity to Consent and Transplants) Regulations 2006, material is part of an organ if it is to be used for the same purpose as the entire organ in the human body.

Performance assessment: This term is intended to encompass use of material in the evaluation and assessment of in vitro diagnostic kits. This is to make it quite clear, for example, that surplus diagnostic tissue can continue to be used to calibrate and assess the comparative performance of medical devices without specific consent.

Post-mortem examination: 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 Consent policy for removal, storage and use of human organs and tissue for scheduled purposes including post mortem

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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.

**Public health monitoring:** Using population-based or epidemiological techniques to ascertain the prevalence, spread and pattern of an established disease or condition in the community, and relating its occurrence to public health programmes and activities.

**Quality assurance:** A programme for the systematic monitoring and evaluation of the various aspects of a project, service, or facility to ensure that standards of quality are being met.

**Relevant material:** Defined by the HT Act as material other than gametes, which consists of, or includes, human cells. In the HT Act, references to relevant material from a human body do not include: (a) embryos outside the human body, or (b) hair and nail from the body of a living person. See policy guidance on how to apply this definition on the HTA's website: [www.hta.gov.uk/policies/relevant-material-under-human-tissue-act-2004](http://www.hta.gov.uk/policies/relevant-material-under-human-tissue-act-2004)

**Research:** A study which addresses clearly defined questions, aims and objectives in order to discover and interpret new information or reach new understanding of the structure, function and disorders of the human body. Research attempts to derive new knowledge and includes studies that aim to generate hypotheses, as well as studies that aim to test them or develop practical applications of new knowledge.

**RNA (ribonucleic acid):** A type of nucleic acid present in the nucleus, and occasionally in the cytoplasm. Cellular forms include ribosomal RNA, messenger RNA and transfer RNA. Messenger RNA can be used to obtain genetic information.

**Scheduled purposes:** Under the provision of the HT Act consent must be obtained to remove, store or use bodies or relevant material for scheduled purposes. The purposes are divided into 2 parts:

Part 1: Purposes requiring consent: General - 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 and quality assurance.

**Stillbirth:** A stillbirth is defined under section 41 of the Registration of Births and Deaths Act 1953 as "where a child issues forth from its mother after the 24 week of pregnancy, and which did not at any time after being completely expelled from its mother, breathe or show any signs of life."

**Surplus tissue:** Includes material which has come from a person's body in the course of his receiving medical treatment, undergoing diagnostic testing, or participating in research; or material that is relevant material that has come from a human body and ceases to be used, or stored for use, for scheduled purposes.

**Tissue:** Any and all constituent part/s of the human body formed by cells.

**Transplantation:** An implant of an organ or part organ, tissue or cells either from and into the same body or from one person to another.
**Valid consent:** Consent which has been given voluntarily, by an appropriately informed person who has the capacity to agree to the activity in question.
19. MONITORING COMPLIANCE AND EFFECTIVENESS

The Pathology Department will undertake an annual local audit to monitoring compliance with the policy and to ensure an audit trail for the retention of tissue and samples.

20. LINKS TO OTHER ORGANISATION POLICIES/DOCUMENTS

- Policy/Guidance for Advance Statements (living wills) about treatment and care
- Protocol for Last Officers (Adults)
- Blood Transfusion Policy
- The Human Tissue Act 2004
- Standard Operating Procedure for Consent (MOR-LP-Consent)
- Relatives Information for Post Mortem Examination
- Access to Health Records Act 1990

21. REFERENCES

- Children Act 1989
- Data Protection Act 1988
- Department of Health Consent guidance
- Department of Health Governance arrangements for NHS Research Ethics Committees
- Department of Health guidance Confidentiality: NHS code of practice
- Disability Discrimination Act 1995
- General Medical Council (GMC) guidance
- General Medical Council (GMC) guidance Consent: patients and doctors making decisions together
- General Medical Council (GMC) guidance 0-18 years: guidance for all doctors
- General Medical Council (GMC) publication Making and using visual and audio recordings of patients
- HTA codes of practice
- HTA Directions
- HTA guidance on Non-consensual DNA analysis
- Human Tissue Act 2004
- Mental Capacity Act (MC Act) 2005
- Mental Capacity Act 2005 code of practice
- Ministry of Justice (MOJ) information on coroners
- National Information Governance Board for Health and Social Care (NIGB)
- National Research Ethics Service (NRES) guidance
- Office of the Public Guardian
- Report of the Joint Committee on Medical Genetics Consent and confidentiality in genetic practice: guidance on genetic testing and sharing genetic information (April 2006)
- Research and the Human Tissue Act - DNA Analysis (October 2007)
- Royal College of Obstetricians and Gynaecologists guidelines Cord blood banking: information for parents
- The National Research Ethics Service (NRES) guidance on model consent forms / information sheets
- The Medicines for Human Use (Clinical Trials) Regulations 2004
- The Human Tissue (Quality and Safety for Human Application) Regulations 2007

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Appendix A

Licensable activities under the Human Tissue Act (section 16)

Subject to Section 16 being brought into force by a relevant Commencement Order or Orders, the following is a full list of the licensable activities contained within Section 16:

(a) the carrying out of an anatomical examination.

(b) the making of a post-mortem examination.

(c) the removal from the body of a deceased person (otherwise than in the course of an activity mentioned in paragraph (a) or (b)) of relevant material of which the body consists or which it contains, for use for a scheduled purpose other than transplantation;

(d) the storage of an anatomical specimen.

(e) the storage (in any case not falling within paragraph (d) of:
   • the body of a deceased person, or
   • relevant material which has come from the body of a deceased person.

(f) 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.
Appendix B

Who are the Nominated representatives?

If a deceased adult had neither consented to, nor specifically refused, any particular donation or the removal, storage or use of their body or tissue for scheduled purposes, those close to them should be asked whether a nominated representative was appointed to take those decisions.

A nominated representative may be empowered to consent to the carrying out of a Post-mortem examination and to the removal, storage or use of the body or tissue for any of the scheduled purposes, other than anatomical examination or public display.

The appointment of a nominated representative and its terms and conditions may be made orally or in writing. The HT Act sets out the requirements for a valid appointment. The appointment of a nominated representative may be revoked at any time.

If the deceased person appointed more than one nominated representative, only one of them needs to give consent, unless the terms of the appointment specify that they must act jointly.

The nominated representative’s consent cannot be overridden by other individuals, including family members. It is advisable, nevertheless, to ensure that appropriate consultation and discussion takes place between all those involved.

The nomination may be disregarded if no one is able to give consent under it. This includes situations where it is not practical to communicate with the nominated representative within the time available if the consent is to be acted upon. In the event that a nomination is disregarded, consent may be given by a person in a ‘qualifying relationship’.

Qualifying relationships

If the deceased person has not indicated their consent (or refusal) to removal, storage or use of their body or tissue for scheduled purposes, or appointed a nominated representative, then the appropriate consent may be given by someone who was in a ‘qualifying relationship’ with the deceased person immediately before their death. These are in order below:

1. spouse or partner (including civil or same sex partner) The HT Act states that, for these purposes, a person is another person’s partner if the two of them (whether of different sexes or the same sex) live as partners in an enduring family relationship.
2. parent or child (in this context a child may be of any age and means a biological or adopted child)
3. brother or sister
4. grandparent or grandchild
5. niece or nephew
6. stepfather or stepmother
7. half-brother or half-sister
8. 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 high up the list refuses to give consent, it is not possible to act on consent from someone further down the list.

If there is no one available in a qualifying relationship to make a decision on consent (and consent had not been indicated by the deceased person or a nominated representative), it is not lawful to proceed with removal, storage or use of the deceased person’s body or tissue for scheduled purposes.

**Children**

Under the HT Act, a child is defined as being under 18 years old

The position of a child who, before they died, was competent to reach a decision and gave consent for one or more scheduled purposes to take place after their death, is no different from that of an adult (the principle of ‘Fraser Ruling’).

If a child consents to a procedure, then this consent carries over into adulthood unless they withdraw their consent.

In some cases, it may be advisable to establish with the person who had parental responsibility for the deceased child, whether the child was competent to make the decision. A person who has parental responsibility will usually, but not always, be the child's parent.

Clearly, in any case where a child has consented to the use of their body or tissue, it is essential to discuss this with the child's family. However, under the HT Act, children cannot appoint nominated representatives and therefore provisions related to seeking consent from nominated representatives do not apply.

Further guidance is included in HTA codes of practice on Post-mortem examination and Donation of solid organs for transplantation.
Licensing and consent flowcharts

Licensing and consent requirements for human tissue for research from the living:

Storage of human tissue from the living

Consent required?
  Yes
  Unless
  • it is obtained before 1 September 2006
  or
  • it is from the living and is non-identifiable to the researcher and is for a specific project approved by a recognised research ethics committee

Licence required?
  Yes
  Unless
  • it is for a specific project approved by a recognised research ethics committee (or pending approval)
  or
  • storage is incidental to transportation
  or
  • it is stored with intent to render acellular

Licensing and consent requirements for human tissue for research from the deceased:

Storage of human tissue from the deceased

Consent required?
  Yes
  Unless obtained before 1 September 2006

Licence required?
  Yes
  Unless
  • it is more than 100 years old
  or
  • it is for a specific project approved by a recognised research ethics committee (or pending approval)
  or
  • storage is incidental to transportation
  or
  • it is stored with intent to render acellular
The link between ethical approval and the licensing and consent exceptions

Use of human tissue in research

Are the samples received from an REC approved tissue bank?

No

HTA licence is not required

Yes

Are the samples being stored for use in a specific project with approval by a recognised research ethics committee?

No

HTA licence is required

Yes

HTA licence is not required

Are the samples from the living AND non-identifiable (e.g. coded) to the researcher?

No

Consent is required

Yes

Consent is not required

Are the samples existing holdings?

No

Yes

Consent is required

Consent is not required
Appendix D

Financial and Resourcing Impact Assessment on Policy Implementation

Summary of Impact Assessment (see next page for details)

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<td>Nil – in house</td>
<td>Nil – in house</td>
</tr>
<tr>
<td>Equipment &amp; Provision of resources</td>
<td>Nil</td>
<td>Nil</td>
<td>Nil</td>
</tr>
</tbody>
</table>

Summary of Impact:
This policy sets out and reinforces the ongoing requirement for consent for removal and storage of human organ and tissue for scheduled purposes.

There will be no additional manpower costs incurred as a result of this policy and staff will undertake the requirements of the policy during their normal working hours. No additional staff will be required to implement the policy.

Training will be provided locally and no additional equipment or resources will be required.

Risk Management Issues:
This policy complied with the requirements of the Human Tissue Act 2009. Local arrangements have been included.

Benefits / Savings to the organisation:
Benefits to the Trust will be that appropriate consent will be obtained and documented in accordance with National guidance.

Equality Impact Assessment
- Has this been appropriately carried out: YES
- Are there any reported equality issues?: NO

If “YES” please specify: not applicable
### Manpower

<table>
<thead>
<tr>
<th></th>
<th>WTE</th>
<th>Recurring £</th>
<th>Non-Recurring £</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Operational running costs</strong></td>
<td>Nil</td>
<td>Nil</td>
<td>Nil</td>
</tr>
<tr>
<td>Additional staffing required - by affected areas / departments:</td>
<td>Nil</td>
<td>Nil</td>
<td>Nil</td>
</tr>
<tr>
<td><strong>Totals:</strong></td>
<td>Nil</td>
<td>Nil</td>
<td>Nil</td>
</tr>
</tbody>
</table>

### Staff Training Impact

<table>
<thead>
<tr>
<th></th>
<th>Recurring £</th>
<th>Non-Recurring £</th>
</tr>
</thead>
<tbody>
<tr>
<td>Affected areas / departments</td>
<td>Nil</td>
<td>Nil</td>
</tr>
<tr>
<td>e.g. 10 staff for 2 days</td>
<td>Nil</td>
<td>Nil</td>
</tr>
<tr>
<td><strong>Totals:</strong></td>
<td>Nil</td>
<td>Nil</td>
</tr>
</tbody>
</table>

### Equipment and Provision of Resources

<table>
<thead>
<tr>
<th></th>
<th>Recurring £</th>
<th>Non-Recurring £</th>
</tr>
</thead>
<tbody>
<tr>
<td>Accommodation / facilities needed</td>
<td>Nil</td>
<td>Nil</td>
</tr>
<tr>
<td>Building alterations (extensions/new)</td>
<td>Nil</td>
<td>Nil</td>
</tr>
<tr>
<td>IT Hardware / software / licences</td>
<td>Nil</td>
<td>Nil</td>
</tr>
<tr>
<td>Medical equipment</td>
<td>Nil</td>
<td>Nil</td>
</tr>
<tr>
<td>Stationery / publicity</td>
<td>Nil</td>
<td>Nil</td>
</tr>
<tr>
<td>Travel costs</td>
<td>Nil</td>
<td>Nil</td>
</tr>
<tr>
<td>Utilities e.g. telephones</td>
<td>Nil</td>
<td>Nil</td>
</tr>
<tr>
<td>Process change</td>
<td>Nil</td>
<td>Nil</td>
</tr>
<tr>
<td>Rolling replacement of equipment</td>
<td>Nil</td>
<td>Nil</td>
</tr>
<tr>
<td>Equipment maintenance</td>
<td>Nil</td>
<td>Nil</td>
</tr>
<tr>
<td>Marketing – booklets/posters/handouts, etc</td>
<td>Nil</td>
<td>Nil</td>
</tr>
<tr>
<td><strong>Totals:</strong></td>
<td>Nil</td>
<td>Nil</td>
</tr>
</tbody>
</table>

- Capital implications £5,000 with life expectancy of more than one year.

Funding /costs checked & agreed by finance:
Signature & date of financial accountant:
Funding / costs have been agreed and are in place:
Signature of appropriate Executive or Associate Director:
Appendix E
Isle of Wight NHS Trust

<table>
<thead>
<tr>
<th>Document Title:</th>
<th>Consent policy for removal, storage and use of human organs and tissue for scheduled purposes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Purpose of document</td>
<td>To ensure that valid and informed consent is taken appropriately for removal of tissue and human organs</td>
</tr>
<tr>
<td>Target Audience</td>
<td>All clinicians involved in the Consent process</td>
</tr>
<tr>
<td>Person or Committee undertaken the Equality Impact Assessment</td>
<td>Claire Willis, Clinical Risk &amp; Claims Manager</td>
</tr>
</tbody>
</table>

**Equality Impact Assessment (EIA) Screening Tool**

1. To be completed and attached to all procedural/policy documents created within individual services.

2. Does the document have, or have the potential to deliver differential outcomes or affect in an adverse way any of the groups listed below? **NO**

   If no confirm underneath in relevant section the data and/or research which provides evidence e.g. JSNA, Workforce Profile, Quality Improvement Framework, Commissioning Intentions, etc.

   If yes please detail underneath in relevant section and provide priority rating and determine if full EIA is required.

<table>
<thead>
<tr>
<th>Gender</th>
<th>Positive Impact</th>
<th>Negative Impact</th>
<th>Reasons</th>
</tr>
</thead>
<tbody>
<tr>
<td>Men</td>
<td></td>
<td>√</td>
<td></td>
</tr>
<tr>
<td>Women</td>
<td></td>
<td>√</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Race</th>
<th>Positive Impact</th>
<th>Negative Impact</th>
<th>Reasons</th>
</tr>
</thead>
<tbody>
<tr>
<td>Asian or Asian British People</td>
<td></td>
<td>√</td>
<td></td>
</tr>
<tr>
<td>Black or Black British People</td>
<td></td>
<td>√</td>
<td></td>
</tr>
<tr>
<td>Chinese people</td>
<td></td>
<td>√</td>
<td></td>
</tr>
<tr>
<td>People of Mixed Race</td>
<td></td>
<td>√</td>
<td></td>
</tr>
<tr>
<td></td>
<td>White people (including Irish people)</td>
<td>Sexual Orientation</td>
<td>Age</td>
</tr>
<tr>
<td>--------------------------------------</td>
<td>---------------------------------------</td>
<td>--------------------</td>
<td>-----</td>
</tr>
<tr>
<td>People with Physical Disabilities,</td>
<td>√</td>
<td>Transgender</td>
<td></td>
</tr>
<tr>
<td>Learning Disabilities or Mental</td>
<td></td>
<td>Lesser, Gay men</td>
<td></td>
</tr>
<tr>
<td>Health Issues</td>
<td></td>
<td>and bisexual</td>
<td></td>
</tr>
<tr>
<td>Children</td>
<td>√</td>
<td>Older People (60+)</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Younger People (17 to 25 yrs.)</td>
<td>√</td>
</tr>
<tr>
<td>Pregnancy &amp; Maternity</td>
<td>√</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Equal Opportunities and/or improved</td>
<td>√</td>
<td></td>
<td></td>
</tr>
<tr>
<td>relations</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

To ensure that staff are have an awareness of the different faith groups they come into contact with when dealing with consent and have considered this need and do not intend to discriminate. The Chaplaincy or Bereavement Office will be able to advice on this matter. In these cases the Coroner has total jurisdiction.

Notes:
Faith groups cover a wide range of groupings, the most common of which are Buddhist, Christian, Hindus, Jews, Muslims and Sikhs. Consider faith categories individually and collectively when considering positive and negative impacts.

The categories used in the race section refer to those used in the 2001 Census. Consideration should be given to the specific communities within the broad categories such as Bangladeshi people and the needs of other communities that do not appear as separate categories in the Census, for example, Polish.

3. Level of Impact

If you have indicated that there is a negative impact, is that impact: Not Applicable

<table>
<thead>
<tr>
<th></th>
<th>YES</th>
<th>NO</th>
</tr>
</thead>
<tbody>
<tr>
<td>Legal (it is not discriminatory under anti-discriminatory law)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Intended</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

If the negative impact is possibly discriminatory and not intended and/or of high impact then please complete a thorough assessment after completing the rest of this form.

3.1 Could you minimise or remove any negative impact that is of low significance? Explain how

Consent policy for removal, storage and use of human organs and tissue for scheduled purposes including post mortem

Version 3.0
3.2 Could you improve the strategy, function or policy positive impact? Explain how below:

3.3 If there is no evidence that this strategy, function or policy promotes equality of opportunity or improves relations – could it be adapted so it does? How? If not why not?

<table>
<thead>
<tr>
<th>Scheduled for Full Impact Assessment</th>
<th>Date:</th>
</tr>
</thead>
</table>

Name of persons/group completing the full assessment.

| Date Initial Screening completed | |
|----------------------------------| |