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HSS(MD)17/2015

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Dear Colleagues

CONSENT FOR HOSPITAL POST-MORTEM EXAMINATION HSC REGIONAL POLICY

In November 2012, the Consent for Hospital Post Mortem Examination HSC regional policy was introduced across Northern Ireland <http://www.dhsspsni.gov.uk/hss-md-48-2012.pdf>. This was developed to standardise policy and practice regarding consent for hospital post mortem examinations and to ensure that all HSC Trusts meet their responsibilities for obtaining valid consent in compliance with the Human Tissue Act.

Since then, the policy has been reviewed by the HSC Bereavement Network and some changes have been necessary to reflect:

- the new training programme introduced in January 2014 on seeking and obtaining consent for hospital post mortem examination <http://www.dhsspsni.gov.uk/hss-md-3-2014.pdf> and;
-
- Departmental guidance issued on death, stillbirth and cremation certification following the Court of Appeal decision on the death of a fetus in utero <http://www.dhsspsni.gov.uk/hss-md-38-2014.pdf> .

The revised HSC regional policy can be accessed at:

http://www.dhsspsni.gov.uk/index/phealth/professional/professional_good_practice_guidelines/postmortem.htm

I would ask you to ensure that it is adopted by your Trust and circulated to relevant staff.

Yours sincerely



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Deputy Chief Medical Officer

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Angela McLernon, NIPEC
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This letter is available on the DHSSPS website at

www.dhsspsni.gov.uk/index/phealth/professional/cmo_communications.htm

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1/04/14	Draft 1.1	HSCBN	Tabled at HSCBN Board meeting for approval. Policy sent to DHSSPS. Amendments from DHSSPS incorporated.
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Consent for Hospital Post-Mortem Examination HSC Regional Policy

1.0 Introduction

This document has been developed to standardise policy and practice regarding consent for hospital post-mortem (PM) examination across all HSC Trusts. It defines accountability for Trusts to ensure they meet their responsibilities for obtaining valid consent in compliance with the Human Tissue Act. Please note that consent is **not** required for Coroner or medico legal PM examination. The detailed procedures for obtaining consent for hospital PM examination are set out in Appendix 1.

This policy has been reviewed and updated to include a new regional mandatory training programme for those who seek consent. (HSS (MD) 3/2014 - Introduction of New Training Programme on Seeking and Obtaining Consent for Hospital Post-Mortem Examination, 27 January 2014)

2.0 Policy Background

Following the Bristol Royal Infirmary Inquiry (1999) and the Alder Hey Inquiry (2001) which led to the Human Organs Inquiry (2001) and the publication of the O'Hara Report (2002) in Northern Ireland, the DHSSPS developed regional guidance, consent forms and accompanying information booklets for relatives on hospital consented post-mortem examination.

The Human Tissue Act was updated in 2004 and became law on 1 April 2006. The Act established the Human Tissue Authority (HTA) to regulate activities concerning the removal, use and disposal of human tissue. The HTA Codes of Practice 1: Consent, 3: Post-Mortem Examination and 5: Disposal of human tissue give practical guidance to professionals carrying out activities which lie within the remit of the HTA (See **8.0**).

3.0 The Purpose

The Human Tissue Authority (HTA) requires Trusts to have a policy on consent for hospital PM examination. The HTA regulates hospital PM examination process including the removal, storage, use and disposal of human tissue and the training requirements for those involved in seeking consent. Trusts require a licence from the HTA to carry out PM examinations and other licensable activities and are inspected by them.

4.0 Scope of the Policy

This policy applies to:

- Health care professionals who seek to obtain consent for hospital PM examination
- Members of staff who support the consent process
- Pathologists
- Trust Bereavement Coordinators
- Mortuary staff

5.0 Policy Objectives

- To comply with the Human Tissue Act and HTA codes of practice
- To ensure that where possible, the wishes of the deceased person and those close to them are known, understood and taken into account
- To ensure that hospital PM examinations are undertaken with appropriate consent and within the stipulations of the consent
- To ensure that there is clear documentation of the family's wishes on the retention, use and disposal of organs and tissue
- To ensure that organs and tissue are only retained with consent
- To promote good communication between all parties involved and ensure that the family are treated with sensitivity and compassion which acknowledges the loss they have experienced

6.0 Policy Statement

That HSC Trusts are committed to ensuring that consent is obtained for all hospital PM examinations in compliance with the Human Tissue Act. This policy should be read in conjunction with relevant legislation, policy, procedure, protocol and guidelines (See 8.0).

7.0 Roles and Responsibilities

7.1 Designated Individual (DI) is the named person on the HTA licence who has a statutory responsibility under the Human Tissue Act 2004 to:

- Supervise the licensed activities carried out within the Trust
- Ensure that appropriate practices are carried out by those working under the HTA licence
- Ensure that the premises are suitable and comply with the conditions of the licence
- Ensure that professionals seeking consent for hospital PM examination receive the required training and conduct the consent process to HTA standards
- Arrange for an annual audit of consent forms to be carried out to assess compliance with HTA requirements and to identify further training needs.

7.2 HSC Trust Director/License Holder is responsible for ensuring that this policy is disseminated to all relevant staff and that training slots are made available in their directorate/division.

7.3 The Pathologist has a statutory responsibility under the Human Tissue Act 2004 to:

- Conduct a hospital PM examination lawfully, which includes being satisfied that valid consent has been obtained
- Give guidance to the professional seeking consent and advise on the usefulness of a limited hospital PM examination, if this is what the relative has chosen
- Provide relatives with further information when requested, and address their questions / concerns (usually in paediatric cases)
- Provide training for relevant professionals on the hospital PM examination procedure, as required
- Facilitate the attendance of relevant professionals at a hospital PM examination, as required

- Prepare the final report when the hospital PM examination is complete and provide a copy to hospital consultant
- Provide preliminary findings to the patient's consultant as soon as possible after the hospital PM examination

7.4 The Healthcare Professional seeking informed consent for hospital PM examination has a responsibility to:

- Complete hospital PM examination consent training as required by HTA, every three years (see Appendix 3 paragraph 1.2)
- Have a thorough knowledge of the consent process
- Seek valid, informed consent from a person in a **qualifying relationship** with the deceased (see Appendix 1 paragraph 3.1.2) and:
 - Explain the value of a hospital PM examination to them
 - Provide them with the relevant information booklet
 - Complete the correct consent form with them
 - Record all consent decisions accurately
 - Inform them of approximate time (if available) of the hospital PM examination
 - Inform them how the results will be communicated
- Schedule the hospital PM examination with the pathologist
- Complete a clinical summary and forward to the pathologist along with the consent form

7.5 The Trust Bereavement Coordinator (TBC) has a responsibility to:

- Deliver training on consent for hospital PM examination in line with HTA requirements
- Audit the consent process for hospital PM examination including the completion and distribution of relevant documentation
- Maintain a register of staff who have completed training
- Work with multi-disciplinary colleagues and service users so that policies, procedures and processes linked to death and bereavement meet national and regional standards, including the HSC Strategy for Bereavement Care.
- Support the Trust's delivery of an efficient and compassionate service to bereaved people

8.0 Source/Evidence Base

8.1 Human Tissue Act 2004 <http://www.legislation.gov.uk/ukpga/2004/30/contents>

8.2 Human Tissue Authority <http://www.hta.gov.uk/>

- Code of Practice 1 - Consent (HTA Version 14.0 July 2014)
- Code of Practice 3 - Post-mortem examination (HTA Version 14.0 July 2014)
- Code of Practice 5 - Disposal of human tissue (HTA Version 14.0 July 2014)
- Policy on consent for post-mortem examination and tissue retention under the Human Tissue Act 2004 (HTA March 2010)

8.3 DHSSPS <http://www.dhsspsni.gov.uk/postmortem>

- Good Practice in Consent for Examination, Treatment or Care (DHSSPS 2003)

- Reference Guide to Consent for Examination, Treatment or Care (DHSSPS 2003)
- HSS (MD) 3/2014 27 January 2014 - Introduction of New Training Programme on Seeking and Obtaining Consent for Hospital Post-Mortem Examination.

9.0 Alternative Formats

This document can be made available on request on disc, larger font, Braille, audio-cassette and in other languages to meet the needs of those who are not fluent in English.

10.0 Dissemination

The Policy will be issued to HSC Trusts for approval and adoption by their policy scrutiny committees and circulated to relevant staff. It will also be available on the Post Mortem Examination section of the DHSSPS website:

<http://www.dhsspsni.gov.uk/postmortem>

Procedure for Obtaining Consent for Hospital Post-Mortem Examination

1.0 Introduction

Hospital post-mortem (PM) examination is important for informing relatives, healthcare professionals and other interested parties about the cause of death. Following a death which does not meet the criteria for referral to the Coroner, the treating clinician may wish to request a hospital PM examination to investigate further the cause of death, to improve knowledge of the disease or effectiveness of the treatment given. Occasionally relatives may request a hospital PM examination.

2.0 Who May Seek Consent?

2.1 It is usually the responsibility of the deceased person's clinician to raise the possibility of a hospital PM examination; however others in the team may be involved in the consent process.

2.2 When considering the hospital PM examination of a child, the decision to approach the parents for consent **must** be made by the child's consultant. If approved, consent **must** be obtained by an experienced clinician.

2.3 The Human Tissue Authority (HTA) requires that anyone approaching relatives to seek consent for hospital post-mortem examination:

"Should be sufficiently experienced and well informed with a thorough knowledge of the procedure. They should be trained in dealing with bereavement, in explaining the purpose and procedures and they should have witnessed a post mortem examination"

Code 1: Consent, para 59 (HTA 2009)

3.0 Who May Give Consent?

3.1 Adults

3.1.1 A decision to consent to or refuse a hospital PM examination can be made by a patient in advance (advance decision) or by a nominated representative who has been appointed by the person while competent. Advance consent can be verbal or written, but must be recorded and signed by two witnesses.

3.1.2 If no advance decision or nominated representative is in place, then the consent of someone in a 'qualifying relationship' must be obtained. The following list gives the order of qualifying relationships (highest first):

- 1) Spouse or partner (including civil or same sex partner)¹
- 2) Parent or child²
- 3) Brother or sister
- 4) Grandparent or grandchild
- 5) Niece or nephew

¹ The Human Tissue 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 In this context a child may be of any age and means a biological or adopted child.

- 6) Stepfather or stepmother
- 7) Half-brother or half-sister
- 8) Friend of long standing

3.2 Children

3.2.1 In the case of a child, consent can be given by a competent child³ before death or by a person with parental responsibility⁴ (nominated representatives do not apply in the case of children).

3.2.2 If a child did not make a decision, or was not competent to make a decision, the appropriate consent will be that of a person with parental responsibility for the child. The consent of only one person with parental responsibility is necessary; however careful thought should be given as to whether to proceed if a disagreement arises between parents.

3.3 Babies

3.3.1 In the case of a baby born alive, which takes a breath and then subsequently dies the possibility of a hospital PM examination should be discussed with the parent(s).

3.3.2 If a baby is born alive, and has taken a breath, the consent of only one person with parental responsibility is necessary; however careful thought should be given as to whether to proceed if a disagreement arises between parents. If this is the case, the hospital PM examination does not have to take place. On completion of the consent form, the mother's signature is essential; however both parents can sign the form.

3.3.3 In circumstances where a baby, capable of being born alive has died in the womb after 24 weeks gestation, the case must be referred to the Coroner, in accordance with Department of Health guidance⁵.

3.3.4 The person seeking consent needs to be aware of the burial or cremation arrangements provided by the Trust, should the parents choose Trust disposal after the completion of the hospital PM examination.

4.0 Discussing the Hospital PM Examination

4.1 People who are bereaved should be treated with respect and sensitivity at all times. They should be given support to help them take important decisions at a difficult time.

4.2 As a first step, a willingness to discuss the possibility of hospital PM examination should be established. If there is an unwillingness to discuss, a note to that effect should be made in the patient's medical records.

³ **Competent child** - Those aged 16 years or over are presumed to be capable of giving consent for themselves – as are younger children who are deemed to have sufficient understanding and intelligence to enable him or her to understand fully what is proposed (sometimes known as Gillick or Fraser competence)

⁴ **Parental responsibility** - The person(s) with parental responsibility will usually, but not invariably, be the child's birth parents. People with parental responsibility for a child include: the child's mother; the child's father if married to the mother at the child's conception, birth or later; or if unmarried if he is named on the child's birth certificate (with effect from 15 April 2002); a legally appointed guardian; the Health and Social Services Trust if the child is the subject of a care order; or a person named in a residence order in respect of the child. A father who has never been married to the child's mother or, after 15 April 2002, whose name has not been included on the child's birth certificate, will only have parental responsibility if he has acquired it through a court order of parental responsibility agreement with the child's mother

⁵ HSS(MD) 38/2014 Guidance on Death, Stillbirth and Cremation Certification following the Court of Appeal decision on the death of a fetus in utero

- 4.3** Whilst it may be perceived that certain religious beliefs or cultural requirements will not allow hospital PM examination, staff should not make this assumption.
- 4.4** Provision must be made to ensure that people who have communication difficulties, or whose first language is not English receive the assistance they require to understand and provide valid consent.
- 4.5** The named next-of-kin in the patient's health record may not be the person in the highest ranking qualifying relationship under the Human Tissue Act. (See Para **3.1.2**) The health care professional therefore needs to determine the person in the highest ranking qualifying relationship. Reasonable efforts should be made to contact the person prior to consent for hospital PM examination being obtained. This information should be documented on the consent form.
- 4.6** At times it may not be possible to obtain consent from the person in the highest ranking qualifying relationship. The Human Tissue 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.
- 4.7** Consent is required from the highest ranking person in the qualifying relationship, however, if there is disagreement between family members of equal rank (e.g. son and daughter), they may need to be given more time and information to help resolve the position. If agreement is not reached the hospital PM examination should not proceed.
- 4.8** Consent is only valid if proper communication has taken place. The doctor/healthcare professional seeking consent should explain the range of choices available, the potential uses for any material retained and the disposal options. It is important to avoid recording contradictory choices e.g. ticking both 'return of organs' and 'hospital disposal'.

The discussion should include:

- The rationale for requesting a hospital PM examination
 - Honest, accurate, clear, objective information
 - The opportunity to ask questions
 - Reasonable time to reach decisions
 - Privacy for discussion with other family members
 - Emotional/psychological support, if required
 - An opportunity for relatives to change their minds within an agreed time limit
 - A realistic timeframe for results and the way in which these will be communicated
- 4.9** Information booklets for relatives which support the consent discussion for baby and child/adult hospital PM examinations are held with the consent forms at ward level. The information booklet for baby hospital PM examination has been translated into ten languages and is available on each Trust intranet for printing out as required. See <http://www.dhsspsni.gov.uk/postmortem>
- 4.10** Relatives should be provided with the name and telephone number of a nominated member of staff whom they can contact if they have further questions.

4.11 The health care professional should contact the pathology department, discuss the hospital PM examination request and confirm the arrangements, including timing and place of examination. It is important for the consent giver to know when the hospital post-mortem examination will take place and when the body can be released, so that they can make arrangements for the funeral.

5.0 Documenting Consent

5.1 Consent Forms for Hospital PM Examination

5.1.2 Two regional consent forms are available (in triplicate) for supporting discussions and recording consent decisions for hospital PM examination and relatives wishes about use, disposal or return of tissue. See <http://www.dhsspsni.gov.uk/postmortem> to view forms.

- ***Consent for Hospital Post-Mortem Examination of Children over 28 days old and Adults.***
- ***Consent for Hospital Post-Mortem Examination of a Baby: Use for intrauterine deaths of babies greater than 6 cms crown rump size (usually more than 12 weeks gestation) and neonates of up to 28 days of age.*** This form is also to be used within neonatal units for babies who die, irrespective of age, as it is more appropriate. This practice has been confirmed by the Regional Paediatric Pathology Department, Belfast.
- A consent form is also available to record ***Consent for Histopathological Examination and Disposal of Early Miscarriages: Use for early pregnancy losses without fetal remains or with a fetus less than 6 cms crown rump size, usually first trimester.***

5.1.3 All decisions should be recorded and the form signed both by the person seeking and the person giving consent.

5.1.4 In addition, details of the discussion should be recorded in the patient's health records.

5.1.5 A detailed clinical history/summary and, if requested, the patient's health records must be sent to the Pathologist and the three copies of the consent forms should be distributed or filed as follows:

- Top copy, with signature in ink, must be sent to the Pathologist
- Middle copy is given to the person giving consent as a record of the decisions he/she made
- Bottom copy should be filed in the patient's health records.

5.1.6 Before the hospital PM examination begins, the Pathologist must check that it has been properly consented to either by the deceased person before they died their nominated representative or an appropriate person in a qualifying relationship to the deceased and that consent has been obtained by an appropriate person.

5.2 Refusal of Consent

- 5.2.1 If the possibility of a hospital PM examination has been discussed with a family and they then decline to give consent, the relevant sections of the consent form should be filled in and signed to record that decision; a copy given to the person from whom consent was sought and the remaining copies filed in the patient's health record. It can be helpful for future conversations with the family if the reason for the decision is also recorded in the health record.
- 5.2.2 If the healthcare professional seeking consent decides that it is not appropriate to ask a family to complete and sign the refusal section of a consent form when they have declined a hospital post mortem examination or if the family / person in qualifying relationship does not wish to discuss this in any detail, the consent seeker **must** clearly record details of the discussion, including the reason for refusal, in the patient's health record.

5.3 Recording and Reporting Changes to Consent Decisions

- 5.3.1 There is a possibility that having completed a hospital PM examination consent form, the consent giver may change their decision and wish to withdraw consent.
- 5.3.2 If this happens the pathologist must be notified **immediately** by the consent taker or the staff member informed of the change.
- 5.3.3 Withdrawal of consent should be recorded in the relevant section of a **new consent form**, and marked '**Withdrawal of Consent**' on the top. The form must be signed by the consent taker and consent giver to record this decision.
- 5.3.4 **For Child / Adult Hospital PM:** All three copies of the consent form are filed in the patient's health records.
- For Baby Hospital PM:** NB As disposal decisions are also recorded on the form, Part 5 **must** be completed and the top copy of the form **must** accompany the baby to the mortuary.
- 5.3.5 A note must also be made in the patient's health record. The top copy of the form must be sent to the pathologist, a copy given to the person from whom consent was sought and a copy filed in the patient's health record.
- 5.3.6 **Please note:** the tradition of burial or cremation taking place within 3 - 4 days of death in NI means that there is not a substantial delay between the receipt of the body and the carrying out of the hospital PM examination (especially within Paediatric Pathology). Families must be informed there will only be a limited time for them to reconsider their decision. A PM examination is usually carried out within 24 - 48 hours of death.

6.0 Information To Be Given To Relatives After a Hospital PM Examination

- 6.1 The health care professional who has requested the hospital PM examination is responsible for ensuring the consent giver is informed of the findings. He/she may be able to give the relatives preliminary information immediately following the hospital PM examination and/or arrange for an appropriate health care professional to meet them at a later stage when the pathologist's full report is available. The clinician needs to explain results using terms that can be easily understood and also be sensitive to the level of detail the family wishes to receive.

7.0 Source/Evidence Base

7.1 Human Tissue Act 2004 <http://www.legislation.gov.uk/ukpga/2004/30/contents>

7.2 Human Tissue Authority <http://www.hta.gov.uk/>

- Code of Practice 1 - Consent (HTA Version 14.0 July 2014)
- Code of Practice 3 - Post-mortem examination (HTA Version 14.0 July 2014)
- Code of Practice 5 - Disposal of human tissue (HTA Version 14.0 July 2014)
- Policy on consent for post-mortem examination and tissue retention under the Human Tissue Act 2004 (HTA March 2010)

7.3 DHSSPS <http://www.dhsspsni.gov.uk/postmortem>

- Good Practice in Consent for Examination, Treatment or Care (DHSSPS 2003)
- Reference Guide to Consent for Examination, Treatment of Care (DHSSPS 2003)
- HSS(MD)3/2014 27 January 2014 - Introduction of New Training Programme on Seeking and Obtaining Consent for Hospital Post-Mortem Examination,

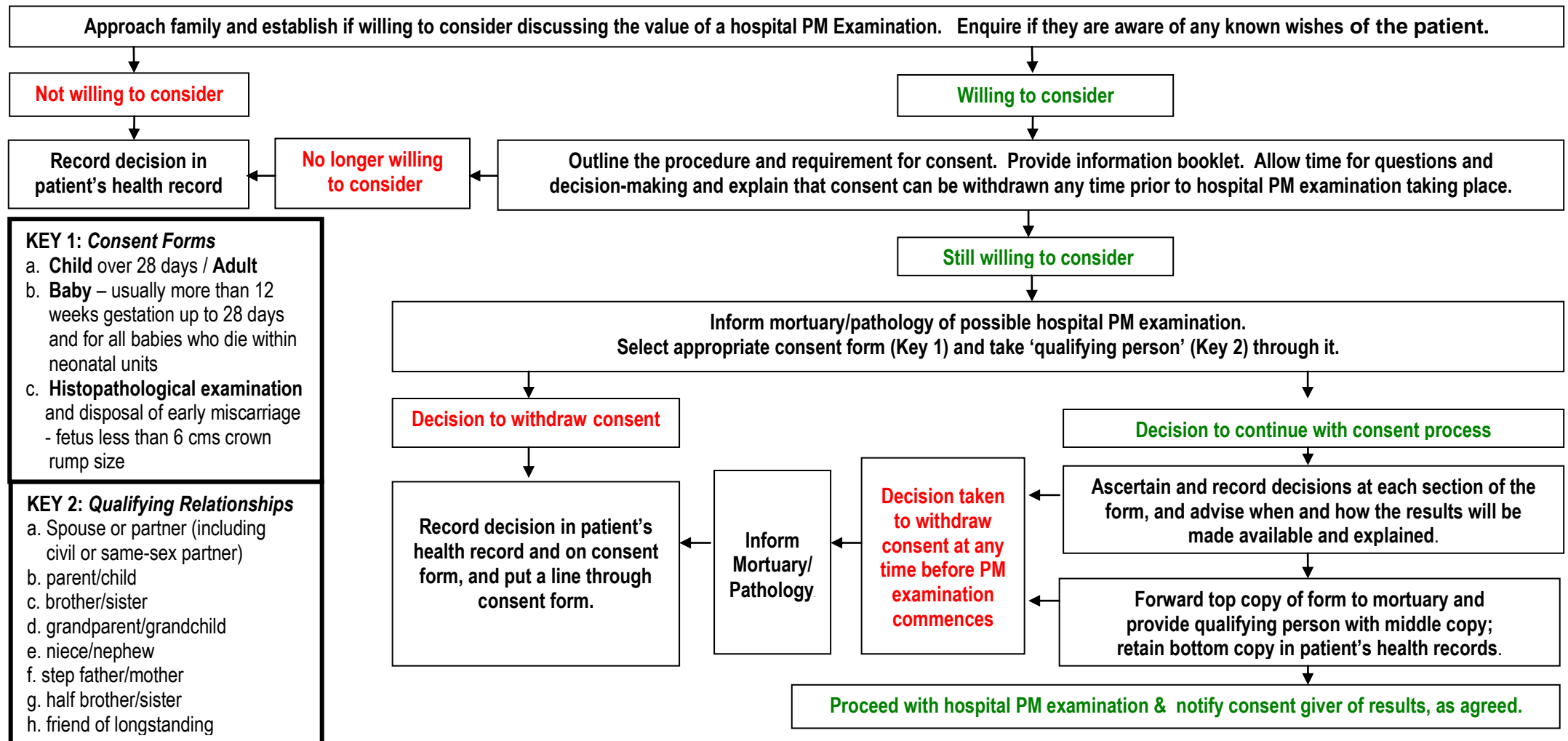
8.0 Further Reading

8.1 Sands - Stillbirth and Neonatal Death Charity

- Guide for Consent Takers: Seeking consent/authorisation for the post mortem examination of a baby (Sands 2013)
- Learning Outcomes for Consent Taker Training (Sands 2013)

PROCESS SUMMARY: CONSENT FOR HOSPITAL POST- MORTEM EXAMINATION

- Consent is necessary for hospital post-mortem examinations, but not for those requested by the Coroner.
- In all hospital post-mortem examinations the family will require oral and written information and support from hospital staff.
- In the first instance, a health care professional who has been involved in the patient's treatment and care will identify the value of requesting a hospital post-mortem examination, whilst appreciating the sensitivities required when communicating with a recently bereaved family.
- It should be ascertained whether any decisions/advance directives regarding hospital post-mortem examinations were made by the patient prior to death.
- The health care professional seeking consent 'should be sufficiently experienced and well informed with a thorough knowledge of the procedure. They should be trained in dealing with bereavement, in explaining the purpose and procedures and they should have witnessed a post mortem examination' *Code 1: Consent, para 59 (HTA 2009)*



Training for Obtaining Consent for Hospital Post-Mortem Examination

- 1.0 A training programme is available to meet the learning requirements identified by the Human Tissue Authority for healthcare professionals who discuss hospital post mortem examination with relatives and obtain consent for this examination.
- 1.1 The training programme is delivered in two parts:
 - Part 1 e-Learning module ***Seeking and Obtaining Consent for Hospital PM Examination*** which is accessible on each Trust intranet. The training includes an overview of the legislative requirements under the Human Tissue Act, the role of the Human Tissue Authority, the responsibilities of staff seeking consent and guidance on completion of consent forms.
 - Part 2: Training Presentation ***Bereavement and Communication: Sensitively Explaining Post Mortem Examination*** which is delivered by Trust Bereavement Coordinators. This presentation will include grief and bereavement, sensitive communication with bereaved relatives, information and support to be provided during the consent taking process and local arrangements / processes for hospital PM examination. A discussion guide on the consent conversation with relatives based on the Calgary Cambridge communication framework is also available for staff.
- 1.2 Healthcare professionals who complete consent forms for hospital PM examination with relatives **must complete** both parts of this training every three years.
- 1.3 The two part programme is also relevant for healthcare professionals who support the consent process through sensitive discussion with relatives eg midwifery and nursing staff.
- 1.4 Healthcare professionals who seek consent for hospital PM examination should arrange attendance at a hospital PM examination as advocated by HTA, if they have not already observed one.
- 1.5 The Bereavement Coordinators in each Trust can be contacted for details on how to access the training programme.