

Chapter 11. Consent

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1. Consent to Post Mortem Examination of Children

- 1.1 In the preceding chapter we concluded that fully informed consent is required and nothing less. Fully informed consent must be freely given without imposition of pressure. It is the application of basic principles of respect for the person, their welfare and wishes.
- 1.2 Comprehensive information is required to obtain a valid consent. Parents must be informed of the identity of each organ to be retained and the purpose for which it is to be used. Dr Peart, a Consultant Paediatric Cardiologist at Alder Hey, accepts that consent forms must be specific about every organ to be retained. Blanket consent is inadequate for organs but is worthy of further consideration with regard to the retention of small tissue samples for diagnostic purposes, medical education and research.
- 1.3 Fully informed consent means that a person must have all the information required to form a final decision. It is not enough for clinicians to tell the next of kin that they would like to examine the body after death and this might involve taking some tissue. The next of kin need to understand what is involved in a post mortem examination, including a description of whole body systems, removal of the brain and the steps necessary to remove various organs, no matter how distasteful the giving of this information might be to the clinician concerned.
- 1.4 Paternalism is defined in the *Concise Oxford Dictionary* as follows,
- ‘the policy of restricting the freedom and responsibilities of one’s dependants in their supposed best interest’
- 1.5 We accept that for some clinicians it might be unpleasant to provide the detailed information necessary to obtain consent. However, their responsibility cannot be avoided. A practical test for the clinician in considering whether he has given full

information is to question whether any significant detail not mentioned could have led to a different decision by the next of kin. If so then the test for fully informed consent will not have been met.

- 1.6 The issue of consent arises at a time of extreme grief. Nevertheless, a post mortem examination should be completed as soon as possible to obtain the best clinical results. It is not possible to allow sufficient time to assuage grief. Therefore, consent must be discussed with sensitivity, openness and the necessary detail to enable clinicians to discharge their duty.
- 1.7 Clinicians agree that they are best placed to obtain fully informed consent. With proper training, they should be able to communicate effectively and sympathetically with the necessary medical knowledge to inform the next of kin. They must understand the value and process of post mortem examination in the clinical setting and also what it means for relatives. We regard it as best clinical practice for clinicians to work closely with pathologists who can assist in determining which organs should be retained for the relevant purposes. They can also assist parents in providing detail relating to the cause of death.
- 1.8 The general public should be educated to understand how human tissue is stored and archived as an ongoing resource for the general benefit of society. For example, the general population benefits from a better understanding of disease and more effective treatment becomes available. The annual influenza epidemic is better managed now than ever before. Researchers are able to access archives to study a previous particular strain of influenza virus and can therefore improve preventative treatment when that strain reappears in any particular year.
- 1.9 If the Liverpool experience represents general practice there must be substantial archives of human material at various locations around the country, most of which have been obtained unlawfully. We cannot undo the wrongs perpetrated in obtaining that material, but can now consider what should happen in the future. In relation to retained organs or tissue it is the right of surviving relatives to request respectful disposal, and they must be given that opportunity. If relatives do not demand respectful disposal, this material may be of great value to society, if it is used for research and education in the future.

2. Consent Forms in the Future

- 2.1 We have considered a number of consent forms for hospital post mortem examination. Until recently all Alder Hey consent forms referred solely to 'tissue' and not 'organs'. The parents are keen to use the terms which are defined by the *Concise Oxford Dictionary* as follows,

‘Tissue: A collection of cells specialised to perform a particular function.

Organ: A part of the body composed of more than one tissue that forms a structural unit responsible for a particular function.’

- 2.2 We have also considered a model consent form contained in the publication by the Royal College of Pathologists in March 2000 entitled ‘Guidelines for the Retention of Tissues and Organs at Post Mortem Examination’. The model is formal and complex.
- 2.3 None of the forms we have seen provide the basis for clinicians to obtain fully informed consent and properly to set out and record the decision. Clear informal language is essential. It appears to us that the more official the form, the less efficient it is in practice. Understanding, particularly in grief, is vital. We suggest a new approach.

3. New Approach to Consent

- 3.1 A more flexible yet formal document is required, setting out all the options clearly. It should be used nationally. The document should be in a question and answer format capable of covering the needs of any individual case. It should be completed jointly by the clinician, a bereavement adviser and the next of kin. We have heard evidence that the specialist cardiac liaison nurses at Alder Hey have successfully taken up a role supporting parents and clinicians in the obtaining of consent. It works well and clinicians, as much as the parents, value the support that this system provides. This role should be performed in a wider context by bereavement advisers and we recommend that it is adopted nationally.
- 3.2 The form will be longer than the existing form. This will allow the questions to be drawn up more sensitively and to cover all areas necessary for fully informed consent. It should include any instruction from the next of kin for final disposal of organs or tissue. The next of kin should be provided with a copy of the document which should be signed by the clinician, bereavement adviser and next of kin. Later sections of the same form could deal with other matters related to the death, with which the bereavement adviser can assist. This written record will ensure that clinicians discharge their responsibility to provide all necessary information to the next of kin. The next of kin can then discharge the responsibility placed upon them by the Human Tissue Act 1961 to make an informed decision.
- 3.3 Once the consent form is signed we favour the next of kin relinquishing further control. This relinquishment is to be subject to the next of kin having the right to specify how, following completion of the purpose for which it was retained, the material should be disposed of respectfully. This is to include their specified religious requirements. We have already stated that the intended use of any organ to be retained must be explained fully to the next of kin. A more liberal attitude should be considered with regard to the

retention and use of tissue, particularly in the form of wax blocks and slides. These are of invaluable benefit for research and teaching. They may also be an important resource for families who may seek access to archived material for the benefit of their family and future generations.

- 3.4 Retained tissue is an invaluable asset for diagnostic as well as research purposes. Once fully informed consent has been obtained for its retention and use, the hospital's undertaking to use it and dispose of the remainder respectfully should be enough. Were it otherwise we would have a situation where clinicians/researchers/teachers would have a difficult obstacle course to negotiate. This could involve repeated requests to parents for additional consent as the original research developed and diversified or as new interests arose. The consent to retain tissue should be general, to permit use within ethically approved research projects so long as it is treated respectfully throughout, including its ultimate disposal.
- 3.5 We set out below an illustration of the content of the consent form we envisage. The list is for discussion purposes and is not prescriptive.

4. National Health Service Hospital Post Mortem Consent Form for Children

4.1 Section 1

Patient Details:

- Name of hospital
- Name of child
- Address
- Date of birth
- Date of death
- Place of death
- Next of kin
- Relationship to child
- Address
- Hospital consultant
- Contact number
- Hospital reference number
- Telephone/fax numbers
- General practitioner
- Address
- Telephone/fax numbers
- Allocated bereavement adviser
- Date of appointment
- Telephone/fax numbers

4.2 **Section 2**

Purpose of hospital post mortem examination to establish:

- Cause of death
- Effects of surgery
- Effects of treatment
- Accuracy of diagnosis

4.3 **Section 3**

Post mortem examination may extend to:

- The whole body
- The chest and abdomen
- Access restricted to a surgical incision
- Small samples from specified organs

4.4 **Section 4**

Consent:

- Consent to full post mortem examination
- Consent can be refused
- Consent can be limited to specified organs

4.5 **Section 5**

Purposes for retaining organs:

- Diagnostic
- Therapeutic
- Medical education
- Research

4.6 **Section 6**

Purposes for retaining tissue:

- Diagnostic
- Therapeutic
- Medical education
- Research
- To enable organs to remain in the body
- To enable organs to be returned to the body for the funeral

4.7 **Section 7**

A request for consent to retention of organs or tissue *following completion* of the Coroner's process should be made *before* the Coroner's post mortem examination is carried out. There should be no distinction in the consent process between organ retention following completion of the Coronial process and a hospital post mortem examination

4.8 **Section 8**

Retention – individual attitudes to the body following death must be identified, acknowledged and respected

Identify, explain and discuss with next of kin:

- Each organ to be retained
- Purpose of retention
- Confirmation that retained organ(s) will only be used for purpose consented to by next of kin
- Whether organs to be examined will be returned to body prior to funeral – if not:
 - How long the funeral would have to be postponed to complete examination before organs can be returned to body
 - Whether next of kin wish to postpone the funeral or not
 - Certificate to confirm organs returned to body prior to funeral to be issued to next of kin
 - Organs retained beyond funeral will be identified and accompanied by signed consent form throughout use for relevant purpose
 - Tissue samples and purpose for retention
 - Whether tissue may be used for therapeutic, medical education or research purposes following diagnostic use
 - Whether next of kin consent to retention of organ or tissue:
 - In a collection
 - In an archive
 - As microscopic samples
 - Date when, place where and by whom ethical approval granted if purpose of retention for research

- Whether organ or tissue can be retained without limit of time for medical education and research so long as it is handled respectfully
- Next of kin have right to give instruction for respectful disposal following completion of purpose for which organ or tissue retained

4.9 **Section 9**

Signatures:

- Next of kin for post mortem examination
- Countersignature of clinician, bereavement adviser or other witness as appropriate
- Date, time and place of signing of consent

We have tried to set out the matters that the clinician must consider in order to obtain fully informed consent from the next kin. The standard is high but achievable given openness, frankness and honesty between clinician and next of kin. We feel that this process can be assisted by the availability of a bereavement adviser, particularly as the next of kin is likely to be suffering a grief reaction. The function of the bereavement adviser is considered in the next chapter.

5. Recommendations

5.1 We respectfully recommend that:

- Following examination of the retained organs or tissue, there should be a meeting between the clinician and parents and referral for genetic counselling or other specialist advice if appropriate.
- Once fully informed consent is obtained for research purposes, the researchers are entitled to remain in possession of the material retained while research continues. We recommend this extends to accessing archives and DNA analysis. All research remains subject to ethics committee approval.
- Local ethics committees be given a supervisory role to police approved research.