

Human Tissue Authority

Code of Practice – Post mortem examination

Code 3 July 2006

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Introduction

- 1 **The Human Tissue Act 2004** (The Act) which extends to England, Wales and Northern Ireland only, sets out a new legal framework for the storage and use of tissue from the living and for the removal, storage and use of tissue and organs from the dead. This includes 'residual' tissue following clinical and diagnostic procedures.
- 2 The Act repeals and replaces the Human Tissue Act 1961, the Anatomy Act 1984 and the Human Organ Transplants Act 1989 as they relate to England and Wales. It also repeals and replaces the Human Tissue Act (Northern Ireland) 1962, the Human Organ Transplants (Northern Ireland) Order 1989 and the Anatomy (Northern Ireland) Order 1992. There is separate legislation for Scotland – the Human Tissue (Scotland) Act 2006 – and the HTA will perform certain tasks on behalf of the Scottish Executive. For the purpose of these codes, the term 'NHS Trusts' includes Health and Social Services (HSS) Trusts in Northern Ireland.
- 3 The Act also establishes the **Human Tissue Authority** (HTA) as the regulatory body for all matters concerning the removal, storage, use and disposal of human tissue (excluding gametes and embryos) for scheduled purposes. This includes responsibility for living donor transplantation. This is one of the functions which the HTA will carry out on behalf of the Scottish Executive.
- 4 The HTA is also responsible for giving advice and guidance on the Act and for licensing establishments that carry out particular activities under the Act.
- 5 One of the HTA's statutory functions is to issue codes of practice. This is one of the first six codes, which should be regarded as complementary:
 - 1 Consent
 - 2 Donation of organs, tissue and cells for transplantation
 - 3 Post mortem examination
 - 4 Anatomical examination
 - 5 Removal, storage and disposal of human organs and tissue
 - 6 Donation of allogeneic bone marrow and peripheral blood stem cells for transplantation.
- 6 These codes give practical guidance to those carrying out activities which lie within the HTA's remit and lay down the standards expected. These are not a definitive guide to the law and licence holders should refer to the Act and keep themselves informed about future legal developments.
- 7 The guidance given applies to anyone undertaking relevant activities. Failure to follow this guidance is not in itself a criminal offence under the Act, but the HTA may take any such breach into account when carrying out its responsibilities in respect of licensing.

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- 8 The codes have been approved by the Secretary of State and laid before Parliament in accordance with Section 29 of the Act.
 - 9 Any references to the terms 'tissue', 'organ', 'part organ', 'material,' 'body parts' or 'cells' in this code refers to 'relevant material'. For definitions of terms used, please refer to the glossary at the back of this code.

Scope of the code

- 10 This code updates and replaces *Families and post mortems: a code of practice* issued by the Department of Health in April 2003¹.
- 11 Post mortem examination is crucially important for informing relatives², clinicians and legal authorities about the cause of death. It can also inform bereaved people (should they wish to know) about possible acquired or genetic diseases which may need treatment and care. More generally, post mortem examination is important in improving clinical care, maintaining clinical standards, increasing our understanding of disease, preventing the spread of infectious diseases and in supporting research and training.
- 12 Bereaved people should be treated with respect and sensitivity at all times, both to help them take important decisions at a difficult time and to ensure continuing improvements in care. The standards expected when seeking and obtaining consent are touched on in this document, but set out in much greater detail in the HTA's *Code of practice on consent*.
- 13 This code sets out recommended practice for all those who communicate with relatives of children and adults who may undergo or have undergone a post mortem examination (whether or not ordered by the coroner). This also includes communication after pregnancy loss.
- 14 The code seeks to ensure that:
 - those close to the deceased person are given the opportunity to understand the reasons for hospital and coroners' post mortems, the processes involved, and their rights in the decision-making process
 - the wishes of the deceased person and those close to them are known and fully understood
 - organs and tissue are only retained following post mortem with consent or other lawful authorisation (such as that of the coroner) and
 - general information about post mortem examinations is readily accessible.
- 15 The code does not deal with body parts or organs held for the purpose of anatomical examination. If the person who has died expressed a wish that their body should be used for anatomical purposes, it will not be possible to carry out that wish if the body has been subject to a post mortem examination or if any organs except the eyes have been removed for transplantation. (Carrying out a post mortem examination does not rule out organ donation for transplantation.) These exclusions may need to be explained to the deceased person's relatives.

¹ This code will also replace a Northern Ireland version of the code, 'Post Mortem examinations – a code of good practice: rights of patients and relatives: responsibilities of professionals'

² Throughout this code, the term 'relatives' should be taken to include close friends of the deceased person, in cases where there are no relatives

Patients who are dying

- 16 This code does not deal as such with the support and information that hospitals should offer to dying patients³. However, much of the decision-making after death is easier if patients have volunteered their wishes before death or already made the relevant decisions. This is a very sensitive matter that requires careful judgement in each case.
- 17 Where appropriate, hospitals should help dying patients and their relatives to understand what may happen immediately before and after death. While respecting the views of patients who indicate that they do not wish to discuss particular issues, clinicians should seek to ensure that:
- any preferences about what happens immediately before or after a patient's death are identified and understood by staff. Attitudes towards the use of tissue, and especially towards post mortems, can vary widely among cultures and religions. All healthcare professionals must be sensitive to this. However, each case and decision is an individual and personal one, and must be treated as such.
 - NHS Trusts and other establishments should ensure their employees are given the necessary training and support to help them identify and meet the widest possible range of needs and wishes
 - contact is made with a religious representative, if required
 - any decisions of the dying person in respect of organ and tissue donation are recorded, and the relevant procedures understood, including post mortem examination
 - any discussions or preferences about the storage and use of organs or body parts for therapeutic purposes and for medical education or research are recorded, and
 - any wishes are recorded for the disposal of organs and tissue following post mortem examination, including those which may subsequently be used for medical education or research.
- 18 These points also apply to the persons with parental responsibility of terminally ill children, or of babies dying in neonatal intensive care. Although raising these issues is highly sensitive, persons with parental responsibility need to be prepared for what is likely to happen immediately before and after their child's death, and some will wish to discuss specific arrangements.

³ See Department of Health Advice: When a patient dies: advice on developing bereavement services in the NHS (www.dh.gov.uk/policyandguidance/healthandsocialcaretopics/bereavement/).

Post mortem examination (autopsy)

- 19 A post mortem examination (or autopsy) may take place either because the coroner considers it necessary, or because it has been agreed upon by the deceased person or their relatives. This code lays down best practice for communication in both cases.
- 20 In any setting (NHS, academic or other), human tissue or organs may only be removed, stored, or used if appropriate consent has been obtained. Before the post mortem starts, the person obtaining consent should, in collaboration with the pathologist, check that the post mortem examination and any removal, storage or use have been properly authorised. This authorisation will either come from a completed consent form, which must meet the standards required by this code, or from the coroner. (This does not imply that pathologists should necessarily be the ones to seek consent, but they should be involved in the process).
- 21 and that the conditions of the licence are being complied with.
- 22 The Royal College of Pathologists (RCPATH) has produced professional guidelines on autopsy practice which consolidate, update and expand on previous guidance.⁵ Post mortem examination should follow these guidelines.
- 23 The RCPATH guidelines indicate that the removal and storage of tissue blocks and slides for the purposes of audit, teaching, quality assurance and review is normal good practice. The Act does not make any special exemptions from the consent requirements for storing blocks and slides. However, Regulations⁶ made by the Secretary of State exempt from licensing storage of relevant material from the body of a deceased person:
- for use for research which is ethically approved by a Research Ethics Authority (or for which such approval is pending); and
 - for the sole purpose of analysis for a scheduled purpose (excluding research) where the material has come from, and is to be returned to, a licensed premises following analysis.
- 24 Therefore, whilst every effort should be made to explain to those giving consent, that the storage of tissue blocks and slides may be essential to enable a diagnosis to be made and is valuable for review or

Quality standards

- 21 All post mortems must be carried out in premises licensed by the HTA, in accordance with the conditions of the licence. The person to whom the licence applies (the 'Designated Individual'⁴) has a duty to ensure that others carrying out the licensed activity (in this case conducting a post mortem examination) on the premises are suitable persons to do so, that suitable practices are being used

⁴ See Glossary

⁵ *Guidelines on Autopsy Practice*. Royal College of Pathologists 2005 (www.rcpath.org.uk)

⁶ The Human Tissue Act 2004 (Ethical Approval, Exceptions from licensing and Supply of Information about Transplants) Regulations 2006.

audit purposes, specific consent must be obtained to store and/or use tissue (including blocks and slides) for any of the scheduled purposes listed in the Act.⁷

- 25 Relatives may agree to a post mortem examination being carried out to learn more about what caused the death, but may object to tissue being stored and/or used (including tissue blocks and slides). This may limit the usefulness of the post mortem and, if so, this should be explained to them. However, it should not prevent a post mortem being carried out unless the pathologist believes that the examination would be uninformative.
- 26 Medical students, doctors and other healthcare professionals may witness the post mortem examination or a demonstration of the findings for educational purposes and to develop their professional skills. This must also be explained to the deceased person's relatives. All who witness the examination must respect the confidentiality of any information relating to the deceased person.

Coroner's post mortem examination

- 27 Coroners' post mortem examinations are carried out to assist coroners in carrying out their functions.⁸ Although the consent of the deceased person or relatives is not

required, the reasons for the post mortem and the procedures to be followed should be explained sensitively to them. They should be given information about when and where the examination is to be performed and told of their right to be represented at the post mortem by a doctor, if they so wish. Whilst consent is not required for a Coroner's post mortem, the carrying out of the post mortem will need to be licensed by the HTA when the Act comes fully into force.

- 28 Under revisions to the Coroner's Rules made in 2005,⁹ a coroner who orders a post mortem examination and is notified about the retention of organs or tissue for examination has a duty to inform the relatives or personal representative of the deceased person about the following before the post mortem is carried out:
- that the material is being kept
 - the period or periods for which it needs to be kept
 - the options for dealing with the material once it is no longer required for the coroner's purposes. These options are:
 - lawful disposal of the material by burial, cremation or other lawful means
 - return of the material to relatives to make their own arrangements, or
 - storage of the material with appropriate consent for use for medical research or other purposes.

⁷ See Glossary.

⁸ Coroners' post mortems are carried out in accordance with the provisions of the Coroner's Act 1988 and the Coroner's Rules 1984 (amended 2005) and the Coroners Act (Northern Ireland) 1959 and the Coroners (Practice and Procedure) Rules (Northern Ireland) 1963.

⁹ www.opsi.gov.uk/si/si2005/20050420.htm. These Rules do not apply to Northern Ireland – the coroner does not have a duty to inform the relatives or personal representative of the deceased person how long the material is being kept; material is kept for such a period as the coroner thinks fit.

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- 29 Further information about these latter three options is set out in the *Code of practice on removal, storage and disposal of human organs and tissue*.
- 30 The deceased person's relatives may wish to discuss the implications of these options, particularly the last two. A coroner's officer¹⁰ or police officer will usually make contact with the bereaved in coroner's cases, but relatives will need access to people with the appropriate knowledge to talk through any questions or concerns they may have. Local protocols between NHS Trusts and coroners' offices should be developed, which are flexible enough to meet relatives' needs.
- 31 The most appropriate person to speak to relatives about consent issues may vary depending on the nature of the case and their concerns – for example, if they have built up a close relationship with a particular staff member during the deceased person's illness, that staff member may be best placed to discuss these issues. If there are genetic aspects to the deceased person's illness that may affect future generations and make the retention of tissue highly desirable as a potential benefit to other family members, the specialist consultant might be asked to explain these aspects.
- 32 Ideally, a request for consent to eventual retention of organs or tissue following completion of the coroner's process should be made before the post mortem is carried out, following the same practice for hospital post mortem examinations. However, this may be done retrospectively if time or distance does not permit otherwise or if the findings indicate an unforeseen reason for retention.
- 33 There is legal provision for a copy of a coroner's post mortem report to be provided to relatives for a fee. They should be told about this and told when the report will be available, and how to obtain a copy. (No charge is payable for a hospital post mortem report.) Unless the coroner has reason to do otherwise, a copy of the post mortem report should in any case be provided to the deceased person's GP and relatives may wish to discuss the findings with them.
- 34 An inquest may also be necessary following post mortem. If so, the reasons for the inquest and its procedures should be fully and sensitively explained to relatives. A coroner's officer will usually do this.

Hospital post mortem

- 35 A hospital post mortem examination is carried out, with the prior consent of the deceased person, the consent of their nominated representative or the consent of a person in a qualifying relationship (see paragraphs 50 - 55 below), to gain a fuller understanding of the deceased person's illness or the cause of death and to enhance future medical care. During

¹⁰ In Northern Ireland, this is referred to as a Coroner's Liaison Officer.

the post mortem examination, tissue or whole organs (e.g., the heart) may be preserved for diagnosis, therapeutic purposes, future medical education (including assuring the quality of clinical care through audit) or for research. If this happens, it must be in accordance with the provisions of the Act. The valid consent of relatives or those close to the deceased person must be given before the post mortem is undertaken to ensure proper compliance with the Act (unless the person who has died has already made a request – see paragraphs 39–41 below).

- 36 The Act makes it unlawful to store or use the body of a deceased person, or to remove, store or use any material from a deceased person's body, for scheduled purposes without appropriate consent.

Who can give consent?

- 37 As noted above, consent must be obtained for a hospital post mortem and for the removal, storage and use of organs and tissue for scheduled purposes after a hospital post mortem, or after the functions of the coroner have ended in relation to a coroner's post mortem.
- 38 The Act defines 'appropriate consent' differently, depending on whether the deceased person was a child or an adult. The following paragraphs should be read in conjunction with the *Code of practice on consent*.
- 40 There is no legal obligation to obtain consent from the immediate family or others in a qualifying relationship if proper consent from the deceased person (or their nominated representative) is in force. However, hospitals might prefer to discuss this with relatives (or whoever is acting as a person in a qualifying relationship).
- 41 If the family or those close to the deceased person object to the donation, for whatever purpose, when the deceased person (or their nominated representative – see below) has explicitly consented, clinicians should seek to discuss the matter sensitively with them. Relatives 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.

Appropriate consent – adults

- 39 For activities other than public display or anatomical examination (which are dealt with in the *Code of practice on anatomical examination*), 'appropriate consent' means:
- the consent of the deceased person, if they gave or refused consent immediately before death; or, if this does not apply:
 - the consent of a nominated representative appointed by the deceased person to deal with this issue, or
 - if no nominated representative, then the consent of someone who stood in a 'qualifying relationship' to the deceased person immediately before that person died.

Appropriate consent – children

- 42 Under the Act, a child is defined as being under 18 years old.
- 43 For activities other than public display or anatomical examination (which are dealt with in the HTA's *Code of practice on anatomical examination*), appropriate consent means the child's consent if they are competent to do so. In the Gillick¹¹ case, the court held that a child is considered to be competent to give valid consent if they have sufficient intelligence and understanding to enable them fully to understand what is involved. In this context 'appropriate consent' means

¹¹ Gillick v West Norfolk and Wisbech Area Health Authority [1985] 3 All ER 402 (HL).

the consent of the child; or, if they did not give or refuse consent immediately before death:

- the consent of a person with parental responsibility for the child immediately before the child's death, or
- in the absence of a person with parental responsibility, the consent of a person in a 'qualifying relationship' to the child at that time (see paragraphs 50–55 below).

A person who has parental responsibility will usually, but not always, be the child's parent¹².

- 44 If the child was in care, the local authority may have had parental responsibility. However, even if the natural parents do not have that responsibility, they might reasonably expect to be consulted. Wherever practicable, discussion should be with both parents, and both should sign the consent form. If either parent is known to object, a post mortem examination should not be carried out.
- 45 If proper consent from the deceased child for a post mortem or the retention and/or use of organs and tissue for scheduled purposes has been obtained, hospital staff should discuss with the parents how they intend to proceed.
- 46 If the parents of the deceased child or those close to the deceased child object to a post mortem examination when the

deceased child has explicitly consented, clinicians should seek to discuss the matter sensitively with them. They should be encouraged to accept the deceased child's wishes and it should be made clear that they do not have the legal right to veto or overrule those wishes.

Nominated representatives

- 47 Adults may appoint one or more persons to represent them after their death in decisions about post mortem examination and the retention of organs and tissue. Where the deceased person's wishes are not known, and a nominated representative has been appointed, this nominated representative is the person from whom you must seek consent. If someone comes forward as a nominated representative, their authority to act on the deceased person's behalf must be verified, including what decisions they have the authority to make. The Act sets out the requirements for a valid appointment. The appointment of a nominated representative may be revoked at any time.
- 48 The appointment of a nominated representative:
- may be general, or limited to consent in relation to one or more activities
 - may be made orally (when it must be made in the presence of at least two witnesses present at the same time), or

¹² The category of persons with parental responsibility is as set out in the Children Act 1989 as amended. Further guidance is available in the Department of Health's *Reference guide to consent for examination and treatment*.

- may be made in writing, when it must be:
 - signed in the presence of at least one witness who attests the signature, or
 - signed at the direction of the person making the appointment, in their presence and in the presence of at least one witness who attests the signature, or
 - contained in the deceased person's will.

49 If two or more people are appointed, unless the terms of the appointment make it clear that they should act jointly, it should be assumed that they can act individually as well as jointly. The nomination may be disregarded if no-one is able to give consent under it, which includes where it is not reasonably practicable to communicate with the nominated representative within the time available if the consent is to be acted upon.

Qualifying relationships

50 Where the deceased person has not made a decision, and a nominated representative has not been appointed (or has been appointed but the nomination has been disregarded in accordance with paragraph 49), the Act ranks persons in a 'qualifying relationship' in the order set out below. Consent should be obtained from the person ranked highest. (Relationships listed together, for example 'brother or sister', are accorded equal ranking, in which case it is sufficient to obtain consent from just

one of them, provided they are ranked equal highest).

51 The 'ranking' below is intended to help those seeking consent to know who to approach, and in what order (highest first):

- a) spouse or partner (including civil or same sex partner)¹³
- b) parent or child
- c) brother or sister
- d) grandparent or grandchild
- e) niece or nephew
- f) stepfather or stepmother
- g) half-brother or half-sister
- h) friend of long standing.

52 Obtaining consent only makes the activity lawful – it does not mean that it is obligatory.

53 Careful consideration should be given before proceeding on the basis of one person's consent if there are overwhelmingly strong objections. For example, if a spouse or partner has no objections to organs or tissue being used for research, but everyone else in the family strongly objects, going ahead may well do more harm than good.

¹³ Section 54 (8) of the 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.

54 Where there are differences of opinion between people in qualifying relationships, decisions will need to be made on a case-by-case basis, taking into account:

- The views of the highest-ranking person in a qualifying relationship – if, for example, a spouse or partner refuses consent, then that should take precedence even if other family members object to that decision and would give consent.
- The views of other qualifying relatives – if, for example, a spouse consents to use for research but other family members strongly object, the benefits of carrying out the activity should be weighed against the distress and resentment that could be caused by proceeding in the face of strong opposition. This will be especially sensitive where people in equally ranked qualifying relationships disagree.
- The potential benefit to other family members – if, for example, two siblings disagree on whether or not material should be retained, potential benefits to family members (e.g., where genetic information may be of value), make a stronger case for going ahead than where such factors do not apply.

55 An agreed position should be reached by inclusive discussion where possible. This will need careful explanations of the options and the potential benefits of a post mortem and of the retention of organs or tissue. Whilst it may be legally

possible to carry out activities with the consent of the highest-ranking qualifying person, consideration should be given to the possibility of this causing distress and resentment in other family members.

- 56 Although the Act only applies to live births, it is good practice for consent to be obtained from the mother in case of pregnancy loss regardless of gestational age
- 57 Asking parents to agree to a post mortem examination of their baby or young child is particularly difficult. The Stillbirth and Neonatal Death Society (SANDS) has published specific and detailed guidance for healthcare professionals on managing pregnancy loss and the death of a baby.¹⁴ The Department of Health video *Respect for the dead; care for the living* is also a useful aid when discussing this topic.

Discussing the post mortem with the family: who may seek consent?

58 The way in which a post mortem examination is discussed with the deceased person's relatives or close friends is extremely important. They need to be given:

- honest, clear, objective information
- the opportunity to talk to someone they can trust, and of whom they feel able to ask questions
- reasonable time to reach decisions (about a hospital post mortem and

¹⁴ *Pregnancy loss and the death of a baby: guidelines for professionals*. Nancy Kohner and Alix Henley, SANDS, 1995. Northern Ireland has also produced guidance on this topic: 'Careplan for Women who experience a miscarriage, stillbirth or neonatal death'.

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- about any donation of organs or tissue); privacy for discussion between family members, if applicable and
- support if they need and want it, including the possibility of further advice or bereavement counselling, or psychological support. (Support may be available from an organisation with whom a relative is already in touch, particularly if they have been a long-term carer of the deceased person.)
- 59 Only once relatives have had time to reach a decision should they be invited to sign a consent form.
- 60 Many people have registered on the NHS Organ Donor Register or carry an organ donor card. The deceased person's relatives may be aware of their wishes about donation of organs or tissue for transplantation and may raise this possibility. Discussion about donation should have taken place in the hospital, and relatives may have decided to donate if possible. All efforts should be made to allow those who wish to donate organs or tissue to do so and explanations should be given where it is not possible.
- 61 Where organ or tissue donation is a possibility (and it should be made clear that this will involve storing tissue until it can be used), the staff member talking to the deceased person's relatives should make early contact with the local transplant coordinator for advice. There may be local variations, but every hospital should have clear arrangements in place for contacting the coordination service or otherwise seeking advice.
- 62 Those seeking consent for hospital post mortem examinations should be sufficiently senior and well informed, with a thorough knowledge of the procedure. They should have been trained in the management of bereavement and in the purpose and procedures of post mortem examinations.
- 63 It is usually the responsibility of the deceased person's clinician to seek consent, knowing the medical problems and the unresolved aspects that merit investigation. However, there may be several options for who actually discusses the post mortem and obtains consent, and most will involve a team approach. Every hospital must have an effective and reliable procedure in place. Responsibility for obtaining consent should not be delegated to untrained or inexperienced staff.
- 64 In some hospitals, an appropriately trained individual undertakes the role, with input from the consultant. In others, it may be the consultant or other senior clinician in charge during the patient's last illness, or someone who has been closely involved with the case or has practical experience of such situations. Nurses and midwives may be trained to take on this particular role.
- 65 Wherever possible, consent is best obtained by a person with whom the relatives have established a relationship. If the consultant in charge has not had close

dealings with the patient's family during the last illness, relatives may find it helpful to also have someone present whom they know and trust. However, if a patient has died suddenly, there may be nobody who knows the family.

- 66 Whichever approach is taken, the hospital should have a named individual who can provide support and information to the bereaved if a post mortem examination is required, whether this is requested by a hospital doctor or a coroner. In some hospitals, this person may also be the one responsible for asking for consent (see paragraph 65 above).
- 67 Wherever possible, before the discussion with relatives, the responsible clinician should contact the pathologist who will perform the post mortem examination. They can then give accurate guidance on which, if any, tissue or organs are likely to be retained, for how long and for what purpose. The pathologist should also be available for a discussion with the deceased person's relatives if they wish. If the pathologist is certain that no organs will be retained, then there will be no need to ask relatives to consent to this, and the relevant section of the consent form may be deleted.
- 68 Meetings about the post mortem, including its timing, should take place in a comfortable, private room, away from the clinical area. This is a complex issue and discussions with bereaved relatives should be face-to-face if possible, so that they do

not have any unanswered questions, and all parties are clear about what is agreed.

- 69 If a face-to-face meeting is impossible because relatives cannot attend, consent to a post mortem examination can be given over the phone or by e-mail. The telephone conversation should be accurately recorded and a copy of the consent form and other relevant documentation given to the relative, just as in a face-to-face meeting. Pathologists should satisfy themselves that the consent was appropriate before proceeding with a post mortem examination.

What should the discussion cover?

- 70 Relatives should be offered full and clear information about the purpose of the post mortem examination, the procedures and the range of choices available to them. They may need time to think this over. The cells and tissue of the body deteriorate after death, so if time is short, for example, because an early post mortem will obtain more or better information, relatives should be told what the time limits are and the reasons for them.
- 71 Factual information should be provided in a permanent form so relatives can take it away with them. At the end of the meeting, they should be provided with a permanent record of the discussion, and of the agreement reached. A signed copy should be included in the patient record and/or coroner's file as appropriate.

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- 72 If possible, relatives should be given the option of changing their minds, within an agreed time limit. They should be provided with the name, telephone number and/or e-mail address of the hospital's designated bereavement adviser or equivalent, so they can ask further questions later. Ready access to general explanatory material – e.g., a hospital website – may also be helpful.
- 73 When discussing the post mortem, some people will want to know in considerable detail what will be done to the body. In such cases the procedure should be sensitively, but honestly and fully, explained. Others will not want as much or even any detail. This should be respected.
- 74 The discussion should include:
- a basic explanation of what happens in a post mortem examination (including the removal, storage and use of tissue samples for diagnosis)
 - the benefits of a post mortem examination and the questions to be addressed in this case, and/or the reasons for the coroner's involvement
 - the possible outcome
 - possible alternatives to a full post mortem examination (making clear the limitations to these, and the benefits of a full post mortem)
 - information about tests needed (e.g. histology, toxicology) and whether these might cause delays in the process
 - when, to whom and how the results of the investigation will be made available and explained
 - options for what will happen to the body or remains, and any organs or tissue removed (including tissue blocks and slides), after the examination
 - whether consent is to be given for storage or use of tissue or organs after the post mortem and for what purposes
 - an explanation of the need for any images to be made (including photographs, slides, X-rays and CT scans) and of their use. In accordance with General Medical Council guidance, consent is not needed for the taking of photographs of organs, body parts, or pathology slides. Nor is consent needed to use images for any purpose provided that the images are effectively anonymised before use by the removal of any identifying marks
 - whether organs or tissue can be retained indefinitely for medical research, and whether there are particular uses which relatives would wish to exclude from any general consent given and
 - the timing of burial or cremation so that, where possible, any human material removed can be reunited with the body for burial or cremation, if relatives so wish. This will need to be done in consultation with the pathologist, and in the case of a coroner's post mortem, with the coroner.

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- 75 In some religions (including the Jewish, Muslim and Hindu faiths), it is important that a funeral should take place as soon as possible. In such cases, every effort should be made to carry out a post mortem examination as quickly as possible (if one is required). The views of relatives should be sought on what constitutes a reasonable timeframe. If this is not likely to be practicable, or if organs cannot be returned within that period, this should be explained to relatives. They will need the help of hospital staff to get the necessary certification completed urgently before the funeral.
- 76 In the case of a coroner's post mortem, relatives do not have the option of refusal, but may want to discuss the implications of any consequent delay with the coroner's staff.
- 77 The pathologist conducting a consented post mortem examination may feel that the conditions imposed by relatives call into question or limit the value of the post mortem, or make it difficult for them to carry out a post mortem to a proper professional standard. In such cases, the pathologist should advise relatives of these limitations or, if necessary, that the investigation will not be carried out because it would be uninformative. This eventuality should be explained to relatives at the time of discussion. However, pressure must not be exerted on them as this would render invalid any consent given.
- 78 Consent to the post mortem must be separate from consent to the subsequent removal, storage and use of tissue and organs (including blocks and slides) – i.e. relatives must be clear that these are two separate decisions. Whenever possible relatives should be asked before a coroner's post mortem takes place whether they might agree to the subsequent storage of removed tissue and organs and their use for certain scheduled purposes once the cause of death has been established and the coroner's duties are complete.
- 79 The discussion must make clear to relatives:
- the meaning of the term 'human tissue'; i.e. it includes organs, parts of organs and tissue in various forms, such as frozen sections and samples fixed in paraffin wax
 - the various purposes for which tissue might be kept and
 - their options for giving or refusing consent to storage of any particular organ or tissue, and for any particular use.
- 80 Although healthcare professionals may recognise the need to obtain a speedy decision in order to maximise the benefit from a post mortem examination, it is important that they do not convey to relatives any sense of being rushed. Before the post mortem, relatives may want to spend as much time as possible with the family member who has died and it is important to try to ensure that they have this time. However, if more information

or better results might be obtained from an early examination, then this should be explained.

Cultural traditions and language differences

- 81 Attitudes to post mortem examination, burial, and the use of organs and tissues after death differ greatly. The person providing bereavement support must be fully informed about the values and beliefs of a wide range of cultures and religions, particularly those of their local community.
- 82 All healthcare professionals need to be aware of these values and respond to them sensitively. NHS Trusts must ensure that staff are given the necessary training and support to identify and meet the widest possible range of needs and wishes. Bereaved relatives may not always know what is traditional or customary within the community when a death occurs and may wish for time to talk to other family and community members. However, each case and decision is an individual and personal one, and must be treated as such.
- 83 Valid consent can only be given if proper communication takes place. All NHS Trusts must consider the needs of people whose first language is not English or who have communication difficulties. They should ensure that such people have access to appropriate materials and support – independent translators, for example – so they can understand and participate in any discussions.

Information to be given to relatives after coroner's and hospital post mortem

Results of the post mortem investigation

- 84 There may be occasions where the deceased person expressed a specific wish before death that information should not be shared with relatives and this should be respected. The results of a coroner's post mortem examination can only be given with the permission of the coroner.
- 85 Before any post mortem is carried out, relatives should be told when the results are likely to be available. For a hospital post mortem (and for any post mortem on a baby or child), they should be given an appointment (if they want one) that will allow them to discuss the results with the clinician responsible for the deceased person's care and/or the pathologist or other specialist clinician, where that would be helpful.
- 86 Relatives will usually be anxious to receive the results of the investigation. They will be better able to tolerate any delay if they understand the reasons for it. Hospitals will need to plan for the resource implications of this if it has not been standard practice to date. It is essential that discussion between the clinician and the pathologist takes place before such information is given to bereaved relatives.
- 87 Some relatives will not want to know the results of the post mortem, or will not want to discuss them in detail. Their wishes must be respected. However, they should be offered the opportunity to discuss the results at a later date.
- 88 If a coroner orders a post mortem, it is to identify the cause and circumstances of death, and it should be explained to relatives that the results may be limited in scope. If they want fuller information from a coroner's post mortem, this might be agreed and the necessary consents recorded in advance.
- 89 The coroner should be consulted before information about the examination, or any copy of the report, is made available to anyone. If the death is still subject to an inquest, any such discussion may be inappropriate and should happen only with the coroner's agreement. Relatives should be warned of this eventuality in advance wherever possible. Coroner's Rules regulate access to the post mortem reports provided for coroners, and a fee may be payable for a copy of a report.
- 90 In the case of a full hospital post mortem examination, the results meeting should allow for as wide a discussion as the relatives want. Although in general information about deceased patients should be treated in confidence, in these circumstances the relatives' legitimate wish for relevant information should be met with proper care and sensitivity, subject to any expressed wishes of the deceased person.
- 91 For parents who have suffered pregnancy loss or the death of a baby, the pathology results may raise many issues which it is important for them to discuss as a couple. These issues may require further discussion with other healthcare professionals, such

as a genetic specialist. Parents should be offered the chance to have such a meeting. If they do not feel ready to take up that offer immediately, they should be provided with written contact details so that they can get in touch again at a later date. They should also be told who to contact (and how) if they have questions later on and given details of national and local support agencies.

- 92 With the coroner's permission where required, the parents of a child who has died should be offered a copy of the full pathologist's report. They should be helped to prepare for what such a report may include and a relevant clinician should help them to understand it. This may be appropriate for adult deaths too.
- 93 Subject to the parents' agreeing, the report should also be given to the deceased child's GP and/or treating clinician and to the mother's GP in the case of a neonatal death or stillbirth.

Information about use of donated tissue and organs

- 94 If relatives have given consent to tissue and organs being stored and used after the post mortem, they should be asked if they wish to receive generalised information about the likely use. If tissue may be used for teaching, a leaflet on the value of medical education and the contribution of organs and tissue may be appropriate. The HTA's *Code of practice on removal, storage and disposal of human organs and tissue* discusses this in more detail.

Maintaining proper documentation

- 95 Establishments should ensure that systems are in place to maintain proper records and documentation for all tissue and organs they acquire and/or pass on to others. The Designated Individual named in licences issued by the HTA must ensure that such systems are in place.
- 96 It is important to be able to track what happens to organs and tissue for health and safety reasons – for example, should an infection related to the material occur, resulting in the need to trace people who came into contact with it. Keeping proper records of what happens to donated material also demonstrates proper respect for the donation.
- 97 The duty to create and maintain proper records starts with the establishment where the material is removed from the body. Such initial records should include details of:
- who gave consent
 - exactly what the consent related to and any restrictions on use stipulated during the consent process
 - what processes are applied to the tissue
 - if tissue is transferred, when and to whom and
 - if relevant, when and how disposal is undertaken.
- 98 Of course, tissue may be transferred from one place to another many times. In order to be able to maintain an audit trail, each establishment that handles human organs or tissue must have systems that can record:
- when the material was acquired and from where
 - the uses to which the material is put whilst under the responsibility of the establishment concerned and any processes applied to it and
 - when the material is transferred elsewhere, and to whom.
- 99 European Directive 2004/23/EC which comes into force in April 2006 requires that adequate systems be set up to ensure the traceability of human tissue and cells intended for human application. The Directive will be transposed into law by Regulations.

Disposal of tissue and organs

100 Guidance on disposal is available in the *Code of practice on the removal, storage and disposal of human organs and tissue*.

Obtaining consent

- 101 The validity of consent does not depend on the form in which it is given. The information required and the manner in which the consent is taken and recorded can vary depending on the particular circumstances.
- 102 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. Written consent merely serves as evidence of consent. If it was not given voluntarily by a person with the capacity to do so and with appropriate information, a signature on a form would not make the consent valid.
- 103 Consent may be expressed verbally or non-verbally. An example of non-verbal consent would be where a person, after receiving appropriate information, holds out an arm for blood to be taken. Where consent is obtained for future storage or use of samples, but the consent itself is not a written consent, it is important to keep an appropriate record of the fact that consent has been given and for what purpose(s). This might be noted in the patient record, the laboratory records, or both.
- 104 Whilst there is a need for consistently high standards of communication and record-keeping in discussing and obtaining consent, it is recognised that individual establishments will have different arrangements in place in order to meet their particular needs. For example, an NHS Trust with a specialist research unit attached to it may well wish to specifically explore the possibility of donation for particular research projects. Consent forms for donation for specific projects require ethical approval¹⁵.
- 105 Establishments should design consent forms to suit their own local needs and arrangements. However, the forms should show that at least the issues described in paragraph 74 have been discussed with relatives, and that they understand exactly what they are consenting to. Model consent forms will be available on the HTA's website¹⁶.
- 106 Establishments should make information available in a variety of ways (leaflets, videos, DVDs, etc.) to help people understand what a post mortem entails and why consent is being sought.
- 107 The HTA's *Code of practice on consent* gives more detailed guidance on obtaining consent – including consent for post mortem examination. It emphasises that consent should be seen as part of a process in which individuals, families, or others who are involved in decision-making have an opportunity to listen, discuss, ask questions, understand and choose.

¹⁵ Defined under Regulations 2006 (The Human Tissue Act 2004 (Ethical Approval, Exceptions from Licensing and Supply of Information about Transplants)) to mean approval given by a research ethics authority.

¹⁶ In Northern Ireland, HSS Trusts and other relevant organisations should use the standardised consent forms agreed with the DHSSPS.

108 The guidance in the code is based on these 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 provided where possible and in a variety of formats
- consent must be based on an understanding of what the procedure involves
- consent need not be given in writing to be appropriate and informed
- consent should ideally be generic.

109 It goes on to stress that the way in which the options are discussed with the deceased person's relatives is extremely important. As well as being approached with sensitivity, they should be given:

- honest, clear, objective information
- the opportunity to talk to someone they can trust, and of whom they feel able to ask questions
- reasonable time to reach decisions (about a hospital post mortem and about any donation of organs or tissue)
- privacy for discussion between family members, if applicable and
- support if they need and want it, including the possibility of further advice or psychological support.

Training and support for staff

- 110 Training in effective communication and interpersonal skills is important for the successful implementation of most aspects of this code and to enable clinical and other staff to manage bereavement well.
- 111 The development of local joint protocols between health establishments and the coroner may provide opportunities for considering training needs and opportunities in the round, in liaison with the relevant bodies such as the police and local authority.
- 112 The death of a patient may be distressing not only for relatives, but also for members of the clinical team involved in that patient's care. Their needs should be considered when bereavement services are planned, in training staff in procedures for obtaining consent for post mortem examinations, and in providing support at the time of death.
- 113 Important elements to consider are:
- a supportive working environment and a team or organisational culture in which the impact of loss, and the need for support, are acknowledged
 - opportunities for case review and debriefing
 - access to confidential, non-managerial support and
 - training, so that staff are equipped to manage bereavement and loss and to handle questions on difficult issues that relatives may understandably wish to raise.

Glossary

These terms have been defined with reference to the Human Tissue Act and the HTA's Codes of Practice and should be read in that context.

Allogeneic use: Cells, tissue or organs¹⁷ removed from one person and applied/transplanted into another.

Altruistic non-directed donation A form of non-directed living donation, where an organ or part organ is donated by a healthy person who does not have a relationship with the recipient and who is not informed of whom the recipient will be.

Anatomical examination: Macroscopic examination of the body of a deceased person, or separate parts of such a body, by dissection for anatomical purposes (teaching or studying, or researching into, the gross structure of the human body).

Anatomical specimen: The body of a deceased person, including separated parts of such a body, to be used or in the course of being used for the purpose of anatomical examination. A former anatomical specimen is a deceased body, organ or body part donated for anatomical examination which is held once the examination of the rest of the body has been completed.

Anatomist: An expert in anatomy.

Anatomy: The science of the structure and organisation of the body and its parts.

Anonymisation: is a procedure to ensure that if relevant material is removed from a human body, all necessary steps are taken to prevent identifying the person from whose body the material has come.

Appropriate consent: is defined in the Act by reference to the person who may give consent.

Autologous use: Cells, tissue or organs removed from and applied/transplanted into the same person.

Autopsy: A post-mortem examination.

Biopsy: A procedure where tissue is removed from a living body for examination under a microscope.

Cells: Individual human cells or a collection of human cells when not bound by any form of connective tissue.

Clinical audit: A quality improvement process that seeks to improve patient care and outcomes through systematic review of care against explicit criteria. Stored tissue previously needed for diagnosis, for example, may need to be reviewed as part of this process.

Clinical diagnosis: A process where a disease is identified from medical history-taking, diagnostic tests and physical examination.

¹⁷ Wherever the term 'organ' is referenced, this also includes 'part organs'.

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

Diagnosis: A process where a disease is identified by signs and symptoms, a history and laboratory tests.

Directed donation: A form of donation where a healthy person donates an organ (usually a kidney) or part of an organ (for example liver or lung lobe) to a specific recipient. The recipient could be known to the donor (in the case of genetically or emotionally related donation) or unknown to the donor (in the case of paired / pooled donation).

DNA (deoxyribonucleic acid): the genetic material of humans which is located in the cell nucleus and controls heredity.

Domino donation: When an organ is removed as part of a person's treatment, it may be suitable for transplant into another person (e.g. a heart originally removed from the recipient of a heart and lung transplant).

Donation: The act of donating human tissue, cells or organs for a scheduled purpose.

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

Embryo: means a live human embryo where fertilisation is complete and includes an egg in the process of fertilisation.

Ethical Approval: Defined under Regulations¹⁸ made under Section 1(9) of the Act to mean approval given by a research ethics authority.

Existing holdings: Body of a deceased person or relevant material which has come from a human body held immediately prior to the commencement of section 1 of the Human Tissue Act 2004 for use for a scheduled purpose.

'Gillick'¹⁹ competent (now also referred to as Fraser competent): A test of competence and method of determining the ability of a young person under the age of 16 to make decisions regarding their own healthcare.

Haemopoietic: Relating to the production of blood cells.

Heart-beating donors: This refers to the circumstances where organs and tissue for transplantation are removed from donors fulfilling the nationally agreed and legally defined criteria of brainstem death.

¹⁸ The Human Tissue Act 2004 (Ethical Approval, Exceptions from Licensing and Supply of Information about Transplants) Regulations 2006.

¹⁹ Gillick v West Norfolk and Wisbech Area Health Authority [1985] 3 All ER 402 (HL).

Human application: The use of tissue or cells on or in a human recipient.

Independent Assessor: A person who acts as a trained and accredited representative of the HTA, to conduct an interview and prepare a report in circumstances envisaged under the Regulations²⁰, for some living organ donations for transplantation.

JACIE: Joint Accreditation Committee – International Society for Cellular Therapy and European Group for Blood and Marrow Transplantation.

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

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

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

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

Living donors: The person donating tissue, cells or organs for transplantation. The most common forms are live kidney donation (where one kidney is removed), or live bone marrow donation.

NHS Organ Donor Register: A confidential, computerised database managed by UK Transplant, which holds details of people who have signed up to become organ donors in the event of their death. The register is used after a person has died to help establish whether they wanted to donate and if so, which organs.

Non-directed donation: A form of donation where a person donates tissue, cells or organs to an unknown recipient. Most commonly, this is deceased donation where the organ is allocated to the most suitable person on the transplant waiting list.

Non-heartbeating donation: A form of donation in circumstances where the deceased donor was not ventilated at the time of death. Donation therefore occurs once death is certified following cardiorespiratory arrest (i.e. the donor's heart has stopped beating).

Organ: 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.

Paired donation: Where a close relation, friend or partner is fit and able to donate an organ but is incompatible with the potential recipient, that couple can be matched to another couple in a similar situation, so that both people in need of a transplant receive a compatible organ.

Peripheral blood stem cells: Cells found in the bloodstream which are able to differentiate into all the cell types found in the blood.

Pooled donation: Where a close relation, friend or partner is fit and able to donate an organ but is incompatible with the potential recipient, that couple can be matched to other couples in a similar situation, so that

all people in need of a transplant receive a compatible organ.

Post mortem: Dissection and examination of a body after death, principally in order to determine the cause of death or the presence of disease processes. A hospital post mortem examination is carried out with appropriate consent to gain a fuller understanding of the deceased person's illness or the cause of death, and to enhance future medical care. Coroners' post mortem examinations are carried out under the authority of the Coroner and without consent to assist Coroners in carrying out their functions.²¹

Preservation: The use of chemical agents, alterations in environmental conditions or other means during processing to prevent or retard biological or physical deterioration of cells or tissues.

Processing: All operations involved in the preparation, manipulation, preservation and packaging of tissues or cells intended for human applications.

Procurement: A process by which tissues or cells are made available.

Public display: includes organised displays and exhibitions held in museums, galleries, exhibition venues and educational establishments, but not for the purpose of education or training. This definition is subject to change pending further consideration by the HTA.

²¹ Coroners' post mortems are carried out in accordance with the provisions of the Coroner's Act 1988 and the Coroner's Rules 1984 (amended 2005) and the Coroners Act (Northern Ireland) 1959 and the Coroners (Practice and Procedure) Rules (Northern Ireland) 1963.

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

- (a) embryos outside the human body, or
- (b) hair and nail from the body of a living person.

Research: is concerned with creating new knowledge by addressing clearly defined questions with systematic and rigorous methods. It is about testing innovations or discovering the right thing to do e.g. finding out whether new treatments work and whether certain treatments or models of service delivery work better than others. Research forms the basis of nationally agreed clinical guidelines and standards and is designed to establish best practice.

Research ethics authority: an ethics committee established or person appointed to advise on, or on matters which include, the ethics of research investigations on relevant material which has come from a human body.

Residual tissue: is material left over from a diagnostic or therapeutic intervention.

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

Serious adverse event: Any untoward occurrence associated with the procurement, testing, processing, storage and distribution of tissue and cells that might lead to the transmission of a communicable disease, to death or life-threatening, disabling or incapacitating conditions for patients,

or which might result in, or prolong, hospitalisation or morbidity.

Serious adverse reaction: An unintended response, including a communicable disease, in the donor or in the recipient, associated with the procurement or human application of tissue and cells that is fatal, life-threatening, disabling, incapacitating or which results in, or prolongs, hospitalisation or morbidity.

Stem cell: A precursor cell that can develop into more than one kind of cell. For example, early bone marrow cells can develop into red blood cells, white blood cells or platelets.

Storage: Maintaining the tissue under appropriate controlled conditions.

Surplus tissue: Relevant material which has come from a person's body in the course of his receiving medical treatment, undergoing diagnostic testing, or participating in research.

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

Tissue establishment: A tissue bank or a unit of a hospital or another body where activities of processing, preservation, storage or distribution of human tissue and cells are undertaken. It may also be responsible for procurement or testing of tissue and cells.

Transplant: An implant of an organ, tissue or cells either from and into the same body or from one person to another.

Transplant coordinator: A person who helps a potential transplant recipient to understand the transplant process and also coordinates the transplant evaluation between the dialysis unit, transplant surgeon, and tissue typing laboratory. After a transplant, the nurse provides a communication link between the recipient and the transplant doctors for post-transplant care.

Transplantable material: Defined under Regulations²² made under Section 34 of the Act to mean the whole or part of any of the following organs if it is their function to be used for the same purpose as the entire organ in the human body: kidney, heart, lung or a lung lobe, pancreas, liver, bowel, larynx, face, or limb. Defined in the same Regulations under Section 33 of the Act to mean organs or part of an organ if it is to be used for the same purpose as the entire organ in the human body, bone marrow and peripheral blood stem cells.

Background reading

Learning from Bristol: the report of the public inquiry into children's heart surgery at Bristol Royal Infirmary 1984-1995, Bristol Royal Infirmary, July 2001

Report of the Royal Liverpool Children's Inquiry, January 2001

Department of Health (May 2003) *The investigation of events that followed the death of Cyril Mark Isaacs*; Department of Health Isaacs Report Response, July 2003