

Consent policy for examination, treatment & post mortem

Key messages

- seeking a patient's informed consent is a process, not just a signature
- consent must be informed, voluntary and given by a patient with capacity to do so
- assessment of 'capacity' is decision and time specific
- consent can be withdrawn at any time
- special rules apply for [children, young people](#) and [patients who lack capacity](#)

Summary

1. Health professionals must obtain valid consent before treatment or undertaking a hospital post mortem.
2. Valid consent means from a properly informed person who has the capacity to consent, free of undue influence.
3. Assessment of 'capacity' is a two stage test involving the patient's ability to make this particular decision at this particular time. Where a patient's capacity is in doubt, assessment should be made in writing using the Trust's Mental Capacity Act [assessment form](#). For patients who have no-one to speak for them other than paid staff and where the Trust is proposing 'serious medical treatment', the Trust has a duty to appoint an [Independent Medical Capacity Advocate](#) (IMCA). Refer to section 14 for [telephone numbers](#) for urgent advice.
4. For [adults who lack capacity](#) staff must consult this policy and be aware that the patient may have an [attorney](#), an [Independent Mental Capacity Act Advocate](#) or a [court appointed deputy](#) acting on their behalf.
5. A patient is free and able to change their mind or withdraw their consent at any time. Patients may change their mind over time; it is for the health professional to ensure that the patient wishes to consent or withdraw consent for a procedure.
6. A patient is entitled to refuse consent and may also have made an [advance decision](#) to refuse treatment.
7. In general, consultants, SpRs and specialist nurses may seek consent for elective procedures. In some specialties, other staff may seek consent provided they have been trained to do so and a [consent competency training package](#) has been completed and returned to medical staffing.
8. Young people aged 16-17 are presumed to be able to consent for themselves. Children below 16 may be competent to give consent depending on their maturity and

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the nature of the decision. Where a child is not competent to give consent, only a person (or body) with [parental responsibility](#) may consent on the child's behalf.

9. Consent may be non verbal (e.g. offering a wrist for taking a pulse), oral or written. Not all consent needs to be written but written consent can provide evidence that consent has been discussed with the patient.

10. There are 4 [generic consent forms](#) for use by health professionals: Form 1 (for adults & children); Form 2 (for neurosurgery, spinal surgery and posterior ophthalmic surgery), Form 3 (where a blood transfusion is refused) and Form 4 (for adults who lack capacity to consent). The consent forms are accompanied by a patient information laminate ('Consent') explaining the consent process and the consent form to patients, and a separate guidance note for health professionals.

11. There are also a range of [procedure specific forms](#) available online which combine relevant patient information with the consent form.

12. The Trust also has separate forms for both adult and paediatric hospital post mortems.

13. All consent forms contain reference to specific consents on [CJD](#), medical training and use of tissue for research (in accordance with the Human Tissue Act).

14. For photographs or any consent to audio-visual recordings, written patient consent must be obtained using the Trust's [Consent to Photography or Video recording](#) form. Staff should refer to the Trust's [photographic policy](#) for detailed advice.

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1 Scope

Trust-wide for all staff involved with seeking consent from patients.

2 Purpose

The purpose of this policy is to set out the Trust's approach to seeking consent from patients in connection with their health and care. It covers:

- consent to examination and treatment
- adults, young persons and children
- specialist areas such as hospital post mortems & organ donation
- what to do in the case of problems or disputes

This policy is based on the 'Reference guide to consent for examination or treatment' (Second edition August 2009) published by the Department of Health ('the Reference Guide') and the requirements of the NHS Litigation Authority (NHSLA) and the Care Quality Commission.

3 Definitions

'advance decision to refuse treatment'	means a decision made by a patient to refuse a specific medical treatment in the circumstances set out (previously known as a living will or advance directive)
'a person who lacks capacity'	means as defined in the Mental Capacity Act 2005 as being a person who is unable to make a decision for themselves because of an impairment or disturbance in the functioning of their mind or brain whether permanent or temporary
'child'	means for the purposes of this policy anyone aged below 16 years of age
'Court appointed deputy'	means a person appointed by the Court of Protection to make decisions on behalf of a person who lacks capacity
'Independent Mental Capacity Advocate'	means a person appointed to support the person who lacks capacity and represent their views but who is not empowered to make decisions
'Lasting Power of Attorney'	means a legal document, registered with the Office of the Public Guardian, appointing an attorney to act on the patient's behalf according to the terms of the document

'parental responsibility'	means all the rights, duties, powers, responsibilities and authority which by law a parent has in relation to the child and his/her property. For persons with parental responsibility see appendix 1
'post mortem'	means an internal examination of the body of a person who has died to provide information about illness and the cause of death ¹
'responsible health professional'	means the clinician providing the treatment or investigation [who] is responsible for ensuring that the person has given valid consent before treatment begins, although the consultant responsible for the person's care will remain ultimately responsible for the quality of medical care provided ²
'young person'	means for the purposes of this policy a person aged 16 to 17 years of age (inclusive)

4 Introduction

Patients have a fundamental legal and ethical right to determine what happens to their own bodies (autonomy). Valid consent to treatment or hospital post mortem is therefore absolutely central to all forms of health care.

Seeking consent is also a matter of common courtesy between health professionals and patients. However, English common law goes further and has established the principle that touching a patient without valid consent may constitute the civil or criminal offence of battery. In addition, legislation such as the Mental Capacity Act 2005, the Human Rights Act 1998, the Human Tissue Act 2004 and the consideration of factors involved with Creutzfeldt Jakob Disease, have all had an impact on the current consent process.

The standards expected of health professionals are high. The Reference Guide advises that:

"The standards expected of healthcare professionals by their regulatory bodies may at some times be higher than the minimum required by the law³."

¹ <http://www.hta.gov.uk/licensingandinspections/sectorspecificinformation/postmortem.cfm>

² Reference Guide, paragraph 30 at page 15

³ Reference Guide, page 8

Failure to obtain proper consent, where a patient subsequently suffers harm, can lead to claims of negligence against both the individual and the organisation. It is therefore important that all staff involved in seeking consent from patients understand what is involved; who may seek consent, what 'informed consent' means, how to discuss consent with patients, and what needs to be recorded or written in patient notes.

Special rules apply in the case of young people and children, and for adults or children who lack capacity. These are discussed separately along with specialist areas such as organ donation, hospital post mortems and screening.

It is the responsibility of staff involved in seeking patient consent to ensure they understand the requirements of informed consent, and that the patient has been given all assistance possible to help make his or her decision.

5 Responsibilities

5.1 Clinical staff

The health professional carrying out the investigation, treatment or procedure is responsible for seeking consent as required. Consent for elective procedures must be sought by those staff capable of performing the procedure concerned i.e. a consultant, SpR or specialist nurse (except where it is appropriate for consent to be delegated as set out in section 7).

5.2 Consultants, SpRs, educational supervisors or specialist nurses

are responsible for

- assessing the competency of staff to whom consent may be delegated (where the staff are not capable of performing the procedure concerned) in line with their department's policy and as recorded in the Consent Competency Register
- returning a copy of the consent competency training package to medical staffing (to ensure the individual's training record is updated).

5.3 Clinical directors

are responsible for:

- deciding whether it is appropriate for consent to be delegated in their department
- the delegation of any consent training within their departments to appropriate staff groups as set out in the Consent Competency Register;
- ensuring that their departmental entry on the Consent Competency Register is accurate and that the details are confirmed annually upon request to the patient information team.
- responding to any action highlighted by the annual consent audit and escalating this to the divisional director if required.

5.4 Divisional directors

are responsible for:

- ensuring that the consent process in their division is in line with this policy
- taking appropriate action in response to any matter arising out of the annual consent audit as escalated to them by a clinical director.

5.5 Medical staffing

are responsible for annotating the electronic staff register with details of consent training for junior doctors as submitted to them in consent competency training packages, and for following up any actions arising out of the annual Consent Audit (in relation to lack of training records for a department which would normally delegate consent or absence of an entry regarding an individual's consent training)

5.6 The programme manager for patient information

is responsible for conducting the annual consent audit to monitor implementation of this policy and for maintaining and updating the Consent Competency Register each year.

5.7 The patient safety executive

is responsible for reviewing the results of the annual consent audit and ensuring any recommendations are followed up as required. Any areas for action will be communicated to the relevant clinical director concerned, with escalation to the divisional director and ultimately to the medical director if required.

5.8 The medical director

- has the lead responsibility for consent policy within the Trust
- is responsible for taking action in response to any matter arising out of the annual consent audit as escalated to him by a divisional director.

6 Valid consent

6.1 Valid Consent

Consent is a patient's agreement for a health professional to provide care, treatment or physical investigation. Patients may indicate consent non-verbally (for example by presenting their arm for their pulse to be taken), orally or in writing.

Consent is valid if given voluntarily and by an appropriately informed person who has the capacity to consent to the intervention in question.

A patient who does not understand what the intervention or procedure involves, cannot give consent.

Consent can take many different forms, ranging from the active request by a patient of a particular treatment (which may or may not be appropriate or available) to the passive acceptance of a health professional's advice.

In some cases, the health professional will suggest a particular form of treatment or investigation and after discussion the patient may agree to accept it. In others, there may be a number of ways of treating a condition, and the health professional will help the patient to decide between them.

Some patients, especially those with chronic conditions, become very well informed about their illness and may actively request particular treatments. In many cases, 'seeking consent' is better described as 'joint decision-making': the patient and health professional need to come to an agreement on the best way forward, based on the patient's values and preferences and the health professional's clinical knowledge.

6.2 What does 'voluntarily' mean?

It has long been a principle of English common law that consent must be given freely. This means without pressure or undue influence being brought to bear on the patient. This pressure, or attempt to influence, could come from family members, carers or other health professionals. Any attempt at coercion would invalidate the consent.

The responsible health professional should satisfy him or herself that the patient's decision is truly their own.

Trust staff should be aware of the Trust's [policy on vulnerable adults](#) which aims to protect against abuse. The term 'abuse' has a very wide definition and includes acts of omission and neglect as well as other forms of abuse. Full details are included in the policy.

6.3 Who can give consent?

A person has the potential capacity to consent to an intervention if:

- a) they are the patient; or
- b) someone with parental responsibility for the patient ;
- c) someone authorised to act on the patient's behalf such as an attorney (appointed under a Lasting Power of Attorney or a Court Appointed Deputy – see section 10).

The Mental Capacity Act 2005 lays down clear guidelines for defining the circumstances where a person may lack the capacity to consent. The question of whether a person lacks capacity is both time and decision

specific. This means it is an assessment made at the time the decision needs to be made.

The Trust has implemented specific procedures and guidelines to be followed in the event a patient lacks capacity to consent. Please refer to section 11 and see also the Trust's Mental Capacity Act [assessment form](#).

6.4 The provision of information

The provision of information is central to the consent process. Where relevant, information about anaesthesia should be given alongside information about the procedure.

Before patients can come to a decision about treatment, they need comprehensible information about their condition and about possible treatments or investigations and their alternatives, risks and benefits (including the risks and benefits of doing nothing).

They also need to know whether additional procedures are likely to be necessary as part of the procedure, for example a blood transfusion, or the removal of particular tissue. Once a decision to have a particular treatment/investigation has been made, patients need information about what will happen: where to go, how long they will be in hospital, how they will feel afterwards and so on.

Patients and those close to them will vary in how much information they want from those who want as much detail as possible, including details of rare risks, to those who ask health professionals to make decisions for them. There will always be an element of clinical judgement in determining what information should be given. However, the presumption must be that the patient wishes to be well informed about the risks and benefits of the various options.

In considering what information to provide on risks, it is advisable to inform the person of any 'material, significant or unavoidable' risks, even if small, any alternatives to the procedure as well as the risk(s) incurred by doing nothing. It is advisable that healthcare professionals give information about all significant possible adverse outcomes and make a record of the information given in the patient's notes.

The General Medical Council advises that medical discussions should focus on the 'patient's individual situation and risk to them' and sets out the importance of providing the information in a balanced way, and checking the patient has understood the information.

Where the patient makes clear (verbally or non-verbally) that they do not wish to be given information about the treatment proposed, this should be documented on the consent form (there is a specific place on the form where this can be recorded). It is important for the healthcare professional to consider revisiting this decision as patients' wishes may change over time.

Please also refer to [section 14](#) below on the provision of information to patients in other languages and formats, and for further sources of information which may be helpful.

6.5 Open access clinics

Where patients access clinics directly, it should not be assumed that their presence at the clinic implies consent to particular treatment. Please ensure that patients have all the information they need before proceeding with an investigation or treatment.

Before arrival at clinic, the patient's GP should have briefed the patient about why they have been referred and their likely treatment so that the information process starts before arrival at the hospital. In clinic, the health professional is then expected to give more detail after diagnosis, in the form of a procedure specific consent form, written information sheets or leaflets. The patient will have this information to take away, read and understand at leisure and be able to ask further questions before treatment. The patient will then have adequate time to make the decision.

6.6 Contacting health professionals outside of formal appointments

After an appointment with a health professional in primary care or in out-patients, patients will often think of further questions which they would like answered before they make their decision. Where possible, it is much quicker and easier for the patient to contact the healthcare team by phone than to make another appointment or to wait until the date of an elective procedure (by which time it is too late for the information genuinely to affect the patient's choice).

Consent forms include a section where contact details may be noted. Patient information leaflets and patient letters should include contact details at directorate level.

6.7 The need for written consent

Consent is often wrongly equated with a patient (or relative's in the case of hospital post mortem) signature on a consent form. A signature on a form is not proof of valid consent.

If a patient is rushed into signing a form on the basis of too little information the consent may not be valid, despite the signature. Similarly, if a patient has given valid verbal consent, the fact that they are physically unable to sign the form is no bar to treatment.

It is good practice to seek written consent if any of the following circumstances apply:

- the treatment or procedure is complex or involves significant risks (the term 'risk' is used throughout to refer to any adverse outcome, including

those which some health professionals would describe as 'side-effects' or 'complications')

- the procedure involves general/regional anaesthesia or sedation
- providing clinical care is not the primary purpose of the procedure
- there may be significant consequences for the patient's employment, social or personal life
- the treatment is part of a project or programme of ethically approved research conducted by this Trust.

If the patient has capacity, but has problems reading or writing, the principles of informed consent still apply. Staff should attempt to obtain a unique identifying mark or verbal consent from the patient and document this on the consent form. It would be good practice for the mark to be witnessed by a person other than the clinician seeking consent and for this to be recorded in the patient's case notes.

It will not usually be necessary to document a patient's consent to routine and low-risk procedures, such as providing personal care or taking a blood sample. However, if you have any reason to believe that the consent may be disputed later or if the procedure is of particular concern to the patient (for example if they have declined or become very distressed about similar care in the past); it would be advisable to do so.

6.8 Withdrawal of consent

Patients with capacity may, if they wish, withdraw consent at any time, including after the procedure has started (assuming it is safe and practical to do so). (See also [Refusal of consent](#) and [Advance decisions](#) to refuse treatment).

A patient may utter a cry of pain during a procedure which may be due to discomfort rather than indicating a withdrawal of consent. It is for the practitioner to establish the patient's wishes, assuming at all times it is safe and practical to stop the procedure or treatment at that point. Once a procedure has started, the practitioner should be careful to ensure that the patient has the capacity to withdraw a previously given consent (e.g. the patient may still be affected by anaesthesia).

The practitioner is entitled to continue the procedure if stopping would put the patient's life at risk.

7 Who should seek consent?

7.1 General principles

The health professional carrying out the procedure is ultimately responsible for ensuring that the patient is genuinely consenting to what is being done: it is they who will be held responsible in law if this is challenged later.

Where oral or non-verbal consent is being sought at the point the procedure will be carried out, this will naturally be done by the responsible health professional. However, team work is a crucial part of the way the NHS operates, and where written consent is being sought it may be appropriate for other members of the team to participate in the process of seeking consent.

In general, medical staff at SpR level and above are deemed capable of performing procedures and therefore competent to seek patients' consent. Junior doctors (often referred to as 'FY1 and FY2s') will not be considered competent to seek patient consent unless they have first completed a formal delegated consent training package relevant to the specialty they are working in.

7.2 Delegation of Consent for elective procedures

The Trust follows the principle that written consent for elective procedures will be sought by staff that are capable of performing the procedure. This means that a Consultant, SpR, or, where appropriate, specialist nurse must seek consent for elective procedures.

However, it is recognised that in some specialties it is appropriate for consent to be delegated to a staff member who is not capable of performing the procedure. Senior staff are responsible for assessing the competency of delegated staff. This is discussed in the sections below.

7.3 Consent Competency Register

The Patient Information Team will ask each clinical director annually to advise whether or not consent is delegated in their area, and if so, which staff groups may conduct the training (e.g. consultants, SpRs, educational supervisors or specialist nurses) and for which procedures. The staff groups nominated to conduct the training are responsible for assessing the competency of delegated staff. This information forms the Consent Competency Register maintained by the Patient Information Team.

Individualised [consent competency packages](#) are available (on Connect or ask the Patient Information Team for assistance) to specialties that have chosen to delegate consent to staff that are not competent or capable of performing the elective procedure for which they are seeking consent.

On completion of the consent competency package, the staff member who is delegating should retain one copy, give the second copy to the delegate and

return the third copy **to medical staffing at Box 154** where details of the training given will be entered onto the individual's record on the electronic staff register.

The consent competency training package covers both general consent issues and specific information for the procedure/s for which the delegate will be obtaining consent including:

- Department of Health and Trust requirements
- the stages of seeking consent
- who is responsible for seeking consent
- where written consent may be required
- the process for documenting consent
- communication skills
- the risks, benefits and alternatives relevant to the specific procedure

The 'general principles' form within the consent competency package will only need to be completed by the staff member on their first placement within the Trust. However, the appropriate specialty specific form of the consent competency package must be completed on rotation to each different specialty before the staff member can seek consent. A copy of the form must be sent to medical staffing each time to ensure the individual's staff record is updated.

For further information contact the Programme Manager for Patient Information and Trust Documents, extension 2032.

7.4 Training process for delegation of consent to junior doctors & nurses

Junior doctors (known as FY1 and FY2s) are provided with e learning modules on induction on the general principles of seeking consent for both elective and emergency procedures. Specialty specific consent training is provided by the nominated individuals set out on the Consent Competency Register. Specialist areas will provide training for nursing staff on the general principles of seeking consent for procedures that they are capable of performing.

8 How and when to seek consent: adults and children

8.1 The processes of consent: single and two or more stages

Where a patient formally gives their consent to a particular intervention, this process of providing information, discussion and decision making is part of 'seeking consent'. This process may take place at one time, or over a series of meetings and discussions, depending on the seriousness of what is proposed and the urgency of the patient's condition.

Single stage process

In many cases, it will be appropriate for a health professional to initiate a procedure immediately after discussing it with the patient. For example, during an ongoing episode of care a physiotherapist may suggest a particular manipulative technique and explain how it might help the patient's condition and whether there are any significant risks. If the patient is willing for the technique to be used, they will then give their consent and the procedure can go ahead immediately. In many such cases, consent will be given orally but a written record in clinical notes should still be made.

If a proposed procedure carries significant risks, it will be appropriate to seek written consent, and health professionals must take into consideration whether the patient has had sufficient chance to absorb the information necessary for them to make their decision. As long as it is clear that the patient understands and consents, the health professional may then proceed.

Two or more stage process

In most cases where written consent is being sought, treatment options will generally be discussed well in advance of the actual procedure being carried out. This may be on just one occasion (either within primary care or in a hospital out-patient clinic), or it might be over a whole series of consultations with a number of different health professionals.

The consent process will therefore have at least two stages:

- (i) the provision of information, discussion of options and initial (oral) decision, and
- (ii) the confirmation that the patient still wants to go ahead.

Patients receiving elective treatment or investigations for which written consent is appropriate should be familiar with the contents of their consent form before they arrive for the actual procedure.

They can be invited to sign the form confirming that they wish treatment to go ahead at any appropriate point before the procedure: in outpatients, at a pre-admission clinic, or when they arrive for treatment.

If a form is signed before patients arrive for treatment, however, a member of the healthcare team must check with the patient at this point whether they have any further concerns, questions or whether their condition has changed.

8.2 Confirmation of consent

If a consent form is signed at any time in advance of the day of the procedure, a health professional involved in the patient's care on the day of the procedure should check with the patient or their carer that they still wish to proceed and then they should sign the form to confirm that the patient still wishes to go ahead and has had any further questions answered.

It will be appropriate for any member of the healthcare team to provide the confirmation signature as long as they have access to appropriate colleagues to answer questions they cannot handle themselves. The consent form should be used as a means of documenting the information stage(s), as well as the confirmation stage.

When confirming the patient's consent and understanding, it is advisable to use a form of words which requires more than a yes/no answer from the patient; for example beginning with "tell me what you're expecting to happen", rather than "is everything all right?"

While administrative arrangements will vary, it should always be remembered that for consent to be valid, the patient must feel that it would have been possible for them to refuse or change their mind. It will rarely be appropriate to ask a patient to sign a consent form after they have begun to be prepared for treatment (for example, by changing into a hospital gown), unless this is unavoidable because of the urgency of the patient's condition.

Similarly, if new information becomes available regarding the proposed treatment between the time when consent was sought and the date of the procedure, a member of the healthcare team should inform the patient and reconfirm consent.

8.3 Consent for anaesthesia

Where an anaesthetist is involved in a patient's care, it is their responsibility (not that of a surgeon) to seek consent for anaesthesia, having discussed the benefits and risks.

In elective treatment it is unacceptable for a patient not to have received information about anaesthesia until their pre-operative visit from the anaesthetist: at such a late stage the patient will not be in a position genuinely to make a decision about whether or not to undergo anaesthesia.

Patients should therefore either receive a general leaflet about anaesthesia in outpatients, or have the opportunity to discuss anaesthesia in a pre-assessment clinic.

The anaesthetist should ensure that the discussion with the patient and their consent is documented in the anaesthetic record, in the patient's medical records or on the consent form. Where the clinician providing the care is personally responsible for anaesthesia (e.g. where local anaesthesia or sedation is being used), then he or she will also be responsible for ensuring that the patient has given consent to that form of anaesthesia.

In addition, where general anaesthesia or sedation is being provided as part of dental treatment, the General Dental Council currently holds dentists responsible for ensuring that the patient has all the necessary information. In such cases, the anaesthetist and dentist will therefore share that responsibility.

8.4 Seeking consent in an emergency

A health care professional's legal duty is to care for the patient and take reasonable steps to prolong the patient's life, acting always in the patient's best interests.

The Reference Guide advises that in an emergency, if a decision needs to be made urgently and where there may be doubt as to the appropriateness of treatment, "there should be a presumption in favour of life-sustaining treatment".

Clearly in emergencies, the two stages (discussion of options and confirmation that the patient wishes to go ahead), will follow straight on from each other, and in these situations healthcare professionals should use the patient's medical records to document any discussion and the patient's consent.

The urgency of the patient's situation may limit the quantity of information that they can be given, but should not affect its quality.

If there is any doubt as to which consent form should be used, use Form 4 (for patients who lack the capacity to consent).

For cases of potential suicide, where the patient is unconscious, the Reference Guide advises that the patient "should be given emergency treatment if any doubt exists as to either their intentions or their capacity when they took the decision to attempt suicide".

8.5 Seeking consent from children and young persons

The legal position on consent varies according to the age of the young person.

Young Persons

A young person, aged 16 to 17, is legally presumed to be capable of consenting to their own medical treatment. As with adults, for the consent to be valid it must be given voluntarily, by an appropriately informed young person capable of consenting to that particular intervention. However, if a young person refuses consent, depending on the circumstances, this refusal can be overridden by either a person with parental responsibility or the court (see Refusal to consent to treatment, section 11 below).

The test to establish whether or not a young person has capacity is the same for adults (see sections 5.3 and 10.2). However, if the young person is overwhelmed by the implications of the decision, the Mental Capacity Act does not apply to those aged under 18 and the legality of the treatment will be assessed in accordance with common law principles.

If the young person is capable of giving consent, it is good practice to involve the young person's family in the decision making process. While it is not legally necessary to do so it would be an unusual situation to proceed in

the face of parental opposition and in any such situation staff are advised to consult with senior colleagues and/or the Assistant Director of Medico-Legal and Patient Experience on extension 2123.

Children aged less than 16: Gillick Competence (also known as the Fraser Guidelines)

Children aged under 16 years of age may consent to a proposed medical procedure or the storage and use of their tissue if they are competent to do so. In the Gillick case, the court held that a child is considered to be competent to give valid consent to a proposed intervention if they have sufficient intelligence and understanding to enable them fully to understand what is involved. Seeking consent from children is dealt with in the Department of Health's guide Seeking Consent: working with children.

It is also important to remember that the consent from the child or young person must still be given voluntarily, and free of the influence or pressure from family members or others. The healthcare professional must be satisfied the decision is that of the child or young person concerned.

Treatment of young children who are not Gillick competent

Only people with parental responsibility are entitled to give consent on behalf of their children. Staff must be aware that not all parents have parental responsibility for their children. Details of those persons who have parental responsibility are set out in [appendix 1](#).

If there is any doubt about whether the person with the child has parental responsibility for that child, it is important to establish this before consent can be taken. The consent form asks the person signing the form, where that is not the patient, to confirm that s/he is a person with parental responsibility for the patient concerned. Under the Civil Partnerships Act 2004 civil partners are able to apply for parental responsibility for their civil partner's child.

When babies or young children are being cared for in hospital, it is deemed impracticable to seek parental consent on every occasion for every routine intervention such as blood or urine tests or X-rays. However, you should remember that, in law, such consent is required.

Where a child is admitted, you should therefore discuss with their parent(s) or those with parental responsibility, what routine procedures will be necessary, and ensure that you have their consent for these interventions in advance. If parent(s), or those with parental responsibility, specify that they wish to be asked before particular procedures are initiated, you must do so, unless the delay involved in contacting them would put the child's health at risk.

9 The process for recording consent: generic consent forms

9.1 Use of consent forms

For significant procedures, it is essential for health professionals to document clearly both a patient's agreement to the procedure and the discussions which led up to that agreement. This may be done either through the use of a consent form (with further detail in the patient's medical records if necessary), or for surgical consent through documenting in the patient's medical records that they have given oral consent.

Completing the forms

The standard consent form provides space for a health professional to provide information to patients and to sign confirming that they have done so. The health professional providing the information must be competent to do so either because they themselves carry out the procedure, or because they have received specialist training in advising patients about this procedure, have been assessed and are aware of their own knowledge limitations. Please refer to section 6.4 for provision of information.

If the patient signs the form in advance of the procedure (for example in outpatients or at a pre-assessment clinic), a health professional involved in their care on the day should sign the form to confirm that the patient still wishes to go ahead and has had any further questions answered. Please refer to 8.2 for further information.

'Procedure Completed' stamps

Once the procedure has been completed (in respect of surgical procedures), the front page of the consent form should be stamped 'procedure completed' using the preformed stamp available. This will prevent any risk of the consent form being re-used. The team member will stamp over the printed text on the consent form as indicated and not over any handwritten information. Application of this stamp will be audited in the annual consent audit.

Responsibility of the health professional

It is the health professional's responsibility to:

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

If any member of staff feels he or she is being pressurised to seek consent when they do not feel competent to do so, they should contact the Programme Manager for Patient Information and Trust Documents, extension 2032.

Completed forms

Completed forms must be kept with the patient's medical records. Any changes to a form, made after the form has been signed by the patient, should be initialled and dated by both patient and health professional.

9.2 Generic consent forms

Standard [consent forms](#) and accompanying information laminates are available through Oracle..

There are four versions of the standard generic consent form:

- a) Form 1 for adults and children (a person with parental responsibility must sign where the child or young person cannot give consent for themselves);
- b) Form 2 for neurosurgery, spinal surgery and posterior ophthalmic surgery (relating to 'high risk tissues' and containing additional mandatory questions about CJD)
- c) Form 3 for patients who refuse to have a blood transfusion.
- d) Form 4 for adults who lack the capacity to consent for investigation or treatment

[Procedure specific consent forms](#) for both adults and children also exist and can be developed. Please contact Patient Information on extension 2032 for assistance.

Please refer to the section below on '[Adults who lack capacity](#)' for a detailed discussion relating to Form 4 and for further information.

9.3 Particular consents contained within the generic forms

9.3.1 **Creutzfeldt Jakob disease.** The question in the generic Form 1 follows the national guidance issued in July 2009.

CJD is thought to be caused by the build up of an abnormal protein called a 'prion'. As there is no effective way to decontaminate surgical instruments used on a patient with known or suspected CJD, or who may be 'at risk' of CJD, there is a possibility the prions may remain after normal decontamination. This is particularly important for operations on the brain, spinal cord and back of the eye as these parts of the body contain the largest amount of abnormal prion protein.

Therefore, for patients undergoing neurosurgery, spinal surgery or posterior ophthalmic surgery there is a dedicated consent form, Form 2, which **must** be used. This form contains additional mandatory questions which have been designed to cover all the situations and different groups of people who may be at increased risk of CJD.

What to do if a patient answers 'yes' to a CJD question

If a patient answers 'yes' to **any** CJD question the responsible health professional treating the patient should **immediately inform** Infection Control on extension 3497 (in hours via bleep number 152-198) or the on

call medical microbiologist (out of hours via the hospital contact centre) **and** the theatre co-ordinator **at all times** (24 hour bleep number 152-585). When calling, the member of staff should ensure the patient's casenotes are available.

A positive answer about CJD does not preclude the patient's treatment but may mean special precautions have to be taken with the instruments required.

- 9.3.2 **Consent to involvement of students.** Patients should be informed about the staff involved with their care. Where a student proposes to conduct an examination which is not essential to the patient's care but is solely for training purposes, it is essential to seek consent for this process. If the procedure the student is carrying out is to further the patient's care (such as taking a blood sample) it is also good practice to inform the patient that the clinician is a student although it is not a legal requirement to do so.

9.3.3 Human Tissue Act

The Human Tissue Act 2004 ('the Act') and the Human Tissue (Quality and Safety for Human Application) Regulations 2007 ('the Regulations') set out a 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 deceased. This includes 'residual' tissue following clinical and diagnostic procedures.

The Act established 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** (See points 4.1 & 4.2).

The Act, Regulations and the HTA's Codes of Practice contain consent provisions on:

- the storage and use of relevant material from the living
- the storage and use of the deceased
- the removal, storage and use of *'relevant material' from the deceased.

*Material other than gametes which consists of or includes human cells.

The Trust is licensed to cover specific activities relating to:

- (i) the storage and use of tissue for specific therapeutic uses
- (ii) undertaking research on tissue
- (iii) undertaking of post mortems

Tissue (including blood) removed as part of a procedure or treatment can be anonymised and used for teaching or quality control. Patients are advised as

part of the consent process and documentation that this may occur, however they are not asked for permission.

The Trust requires that patients should be given the opportunity to refuse permission for tissue taken from them during surgery or other procedures to be used for research purposes. The tick boxes on the consent form allow the patient to record their consent to tissue being taken for research. The patient is informed that any tissue (including blood) removed as part of the procedure or treatment will be anonymised and may be used for teaching or quality control.

Explicit consent is not necessary for public health surveillance using the unlinked anonymous method. The only unlinked anonymous surveillance undertaken at the Trust relates to anonymous HIV and hepatitis surveillance. Written information regarding this is available in Clinic 1A.

Tissue samples may be used for quality assurance purposes without requiring specific patient consent provided there is an active policy of informing patients of such use. This is essential to ensure the high quality of service which all patients have the right to expect. Wherever possible, samples of tissue used in this way should be anonymised or pseudonymised.

For further information about obtaining ethical approval for a research project, please refer to:

http://www.cuh.org.uk/research/researchers/starting/normal_application.html

For further information regarding consent and the use of human tissue, please refer to the HTA code of practice for consent:

<http://www.hta.gov.uk/legislationpoliciesandcodesofpractice/codesofpractice/code1consent.cfm>

10 Specialist Consents

10.1 Audio and visual recordings (including photography).

Consent should be obtained for any such recording, including photography, and staff should explain to the patient the purpose and possible future use of the material.

Reference should be made to the Trust's [Photographic Policy and Procedure](#). Photographic and video recordings made for clinical purposes form part of a patient's record. Health professionals should always ensure that they make clear in advance with appropriate written consent, if any photographic or video recording will result from a procedure.

Consented photographic and video recordings which are made for treating or assessing a patient, ie for the patient's medical records, must not be used for any purpose other than the patient's care or the audit of that care. If a member of staff wishes to use such a recording for education, publication or

research purposes, s/he must seek further written consent, ensuring that the person giving consent is fully aware of the possible uses of the material. In particular, the patient must be made aware that it may not be possible to control future use of the material, including the fact that it may not be possible to withdraw, once it has been placed in the public domain.

If a member of staff wishes to make a photographic or video recording of a patient specifically for education, publication or research purposes, s/he must first seek the patient's written consent (or where appropriate that of a person with parental responsibility) to make the recording, and then seek consent to use it.

If a consented recording is taken for teaching purposes and the patient decides that they are not happy for any recording to be used, the consent level will reduce to use in the patient's medical records only.

The surgical consent form requires the patient to tick a box to agree to photography taken for this purpose. Staff must ensure that the person giving consent is fully aware of the possible uses of the material.

Retrospective consent can be obtained in cases where a recording is to be made specifically for education, publication or research purposes but the patient is temporarily unable to give or withhold consent because, for example, s/he is unconscious. In such cases, staff may make such a recording, but must seek consent as soon as the patient regains capacity. The recording must not be used until consent for its use has been received, and if the patient does not consent to any form of use, the recording must be destroyed.

If the patient is likely to be permanently unable to give or withhold consent for a recording to be made, consent should be sought from the next of kin. There must not be any use of the recording which might be against the interests of the patient.

10.2 Post mortems

A hospital post mortem examination can be 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.

When undertaking a post mortem, discussions with the patient or relatives can take place in hospital prior to that person's death. Relatives may know the person's wishes in respect of, for example, donating organs for transplantation. These discussions must be documented.

Families should be given the opportunity to understand why a post mortem is indicated, the process involved and their rights in the decision making. The decision should include:

1. A basic explanation of what happens in a post mortem examination
2. The benefits, possible outcome and possible alternatives
3. Information about tests needed

4. How results of the investigation will be reported
5. Options for what will happen to the body or residual tissue
6. For further information, please refer to paragraph 39 of the code of practice for post mortems:

<http://www.hta.gov.uk/legislationpoliciesandcodesofpractice/codesofpractice/code3post-mortem.cfm>

Who can seek consent?

For post mortem, the person seeking consent for an adult will be one of the Bereavement Care Services Team, adopting a team approach with the clinician who had treated the patient. The person seeking consent for a baby or child will be a clinician from either the Obstetric or Paediatric Department.

Consent to post mortem

Where an adult has, whilst alive and competent, given consent for post mortem following their death, then that consent is sufficient for the activity to be lawful and takes precedence over any one else's wishes.

If the family or those close to the deceased person object to the post mortem being carried out, for whatever purpose, when the deceased person (or his/her nominated representative – see below) has explicitly consented, clinicians should seek to discuss the matter sensitively with them. They should be encouraged to accept the deceased person's wishes and it should be made clear that they do not have the legal right to veto or overrule those wishes.

Tissue from the deceased – nominated representatives

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

Tissue from the deceased – qualifying relationships

If the deceased person has not indicated their consent (or refusal) to post mortem, removal, storage or use of their body or tissue for scheduled purposes, nor appointed a nominated representative (or the nomination has been disregarded), then the appropriate consent can be given by someone in a 'qualifying relationship' to the deceased immediately before their death.

Those in a qualifying relationship to the deceased person are (in order of priority):

- a) spouse or partner (including civil or same sex partner)
- b) parent or child (in this context a 'child' can be any age)
- 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

Tissue from the deceased – children

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

If a child did not make a decision, or was not competent to make a decision, the Act makes clear that 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.

The Trust uses post mortem consent forms based on the model produced by the Human Tissue Authority. Separate consent forms exist for adult and paediatric post mortems. Consent forms are available, together with accompanying post mortem information leaflets, only from the Bereavement Care Team and/or Children's Services.

Contact the Bereavement Care Services Team for information on post mortems on extension 3537.

Right for the person consenting to the post mortem to change their mind

There is a short period in which the person qualified to give consent for post mortem can change their mind or withdraw consent, even after they have signed the form. The healthcare professional taking consent must complete the relevant section on the post mortem consent form, providing a contact name, telephone number and the date and time by which this should be communicated.

10.3 Organ donation

The Trust follows the National Hospital Policy for Organ Donation: http://www.uktransplant.org.uk/ukt/about_transplants/donor_care/policy_documents/uk_hospital_policy_for_donation.pdf

For further information or queries regarding organ donation, contact the Donor Co-ordinators on their 24 hour pager 08700555500 - pager number DC 04.

The Human Tissue Authority has issued a code of practice on donation of organs, tissue and cells for transplantation:

http://www.hta.gov.uk/db/documents/2006-07-04_Approved_by_Parliament_-_Code_of_Practice_2_-_Donation_of_Solid_Organs_200607133233.pdf

10.4 Genetic screening

Screening (which may involve testing) healthy or asymptomatic people to detect genetic predisposition's or early signs of debilitating or life threatening conditions can be an important tool in providing effective care.

Consent to genetic screening differs from the consent of an individual undergoing treatment because there are potential implications of genetic screening. Families are involved and the term 'family' covers extended sets of relatives linked by blood or by marriage. Families may share genetic traits and genetic screening may discover information about people that have never been screened nor consented to screening. Also, a test result will give the individual tested no certain prediction but a range of possibilities that may be quite wide.

Anyone considering whether to consent to screening must be able to make a properly informed decision. As far as possible, it is important to ensure that screening would not be contrary to the individual's interest. Particular attention must be paid to ensuring that the information the person wants or ought to have is identified and provided. The following should be carefully and clearly explained:

- the purpose of the screening
- the condition to which the genetic screening may give rise: how serious is it? How variable is it in its effects? What are the therapeutic options?
- the way in which the disorder is transmitted
- the likelihood of positive/negative findings and possibility of false positive/negative results
- the uncertainties and risks attached to the screening process
- any significant medical, social or financial implications of screening for the particular condition or predisposition
- follow up plans, including availability of counselling and support services
- the procedures for informing individuals of the results, both positive and negative, and what will be done with the samples
- information about the implications of screening positive individuals for their future/existing children and for other family members
- a warning for pregnant women that genetic screening may reveal unexpected or awkward information

When screening children, or adults who are not able to decide for themselves, reference should be made to the relevant previous sections. In appropriate cases, account should be taken of the guidance issued by bodies such as the Advisory Committee on Genetic Testing.

For further information or queries regarding consent to genetic screening, contact Medical Genetics on 2446 or (from outside the Trust) 01223 216446.

10.5 Research

When carrying out or participating in research involving patients or volunteers, it is particularly important to ensure:

- (i) that the research is not contrary to the individual's interests; and
- (ii) that participants understand that it is research and that the results are not predictable.

Research policies within the Trust are informed by the Department of Health's 'Research Governance Framework for Health and Social Care'. This document sets out a framework for the governance of research in health and social care. For further details please visit:

http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_4008777

10.6 Gametes

It is a legal requirement under the Human Fertilisation and Embryology Act 1990 (as amended by the Human Fertilisation and Embryology Act 2008) that consent must be obtained in writing before a person's gametes can be used for the treatment of others, or to create an embryo in vitro. Consent in writing is also required for the storage of gametes. Information and an opportunity to receive counselling must be provided before consent is given. Where these requirements are not satisfied, it is unlawful to store or use the person's gametes for these purposes.

For more guidance please consult the Reference Guide.

11 Adults who lack capacity (Mental Capacity Act 2005 'MCA')

11.1 Introduction

Touching a patient without valid consent may constitute the civil or criminal offence of battery. In most cases gaining valid consent is straightforward, as most patients are clearly able to understand the information presented.

Under English law, no-one can consent on behalf of an adult who lacks capacity **unless**:

- (i) they have been authorised to do so under a Lasting Power of Attorney
- (ii) they have the authority to make treatment decisions as a court appointed deputy.

Subject to the above exceptions, other people including family members, carers or members of the healthcare team cannot consent on behalf of such an adult. The MCA does however contain provisions setting out when it is lawful to carry out examinations or treatment on an adult who lacks capacity.

It is important that all clinicians have a clear understanding of the relevant issues relating to capacity to consent to treatment and how to assess the patient's capacity to make decisions, especially in respect of consent to treatment. If you have any concerns about your ability to adequately assess capacity to consent you must involve a senior colleague.

The Mental Capacity Act has 5 key principles:

1. Presumption of capacity to consent - every adult has the right to make their own decisions.
2. Individuals must be supported to make their own decisions.
3. They have the right to make their own eccentric decisions or what may be seen to be an unwise decision.
4. Anything done for/on behalf of those lacking capacity must be in their "best interests".
5. Anything done for/on behalf of those lacking capacity must be the least restrictive of their basic rights and freedoms.

The scope of the MCA includes all decisions ranging from mental capacity to make day to day decisions to more serious decisions about where to live, whether to have an operation, financial matters, and wills.

11.2 Definition of capacity

The MCA defines a person who lacks capacity as:

"a person who is unable to make a decision for themselves because of an impairment or disturbance in the functioning of their mind or brain."

It does not matter if the impairment or disturbance is permanent or temporary. There is a two stage test to assess capacity:

- (i) is there a disturbance of, or impairment in, the functioning of the person's mind or brain and
- (ii) if so, is the disturbance or impairment sufficient that the person lacks the capacity to make that particular decision?

It is important to note that this is therefore a time and decision specific assessment. It is this particular decision and not decisions in general.

A person is unable to make a decision if they can not demonstrate one or more of the following:

- (i) the ability to understand information;
- (ii) the ability to retain that information;
- (iii) the ability to use or weight the information;
- (iv) the ability to communicate a decision.

The health professional must consider whether the patient is able to:

- understand in simple terms what the treatment is, its purpose and nature and why it is being proposed?
- understand the principal benefits, risks and alternatives of the treatment being proposed?
- understand in broad terms what will be the consequences of not receiving the treatment?
- retain the information for long enough to make an effective decision?

- make a free choice (i.e. free from pressure)?
- communicate their decision, and, if not, can they be helped to do so?

It is important that assessments of capacity are recorded in the medical notes and Form 4 is completed. The identity of the clinician making the assessment must be recorded. In more complex cases, the assessment should be made by one of the more senior doctors in the team, bearing in mind the possible legal consequences. Guidance on assessing capacity is given in Chapter 4 of the MCA Code of Practice.

In assessing a patient's capacity, clinicians must use the Trust's [MCA assessment form](#).

11.3 Patients who lack capacity

If a patient appears to lack capacity to consent to treatment, first consider whether anything can be done to improve the situation.

For example, for patients with learning disabilities, the presentation of pictorial materials and repeating the explanations are often useful. If patients are receiving sedation, this may need to be reviewed or reduced. Consider involving specialist colleagues, such as learning disability teams or speech and language therapists, unless the urgency of the situation prevents this.

For patients who do not speak English as a first language, an interpreter may be needed. Sometimes it will be a question of waiting and giving the patient sufficient time to consider. Other members of the clinical team may contribute by helping the patient to absorb the information and reflect upon it.

In either of the above situations, consider whether the Trust's [Hospital Communication Book](#) may help with pictures and translations of some key hospital situations.

For patients where a procedure is carried out without consent because of incapacity, Consent Form 4 should be completed.

In the absence of capacity and in the absence of any earlier valid advance direction from the patient, there is a duty of care to take such action as is immediately necessary to preserve life or prevent deterioration, so long as such action is judged by the clinician to be in the best interests of the patient.

In the case of a proposed sterilisation operation for an individual who lacks the capacity to make a decision about this procedure, applications should first be sought from the Family Division of the High Court. Contact the Assistant Director of Medico-Legal and Patient Experience on extension 2123 for advice and to arrange for application.

11.4 Lasting Power of Attorney (LPA)

An adult over 18 years of age may appoint an attorney to look after their health and welfare decisions. Known as a 'personal welfare LPA', it authorises the attorney to make decisions, according to the terms laid down, as valid as if they were made by the person themselves.

There are prescribed forms and criteria which such appointments must meet. These are laid down by the Office of the Public Guardian

www.publicguardian.gov.uk

Staff should ask to receive a copy of the LPA to understand the extent of the appointment. More information is available from the Public Guardian's office.

Staff should also be aware that a patient may appoint more than one attorney to act on his or her behalf. Unless the patient has specified otherwise, any such attorneys should act jointly. For specific guidance please seek advice from the Assistant Director of Medico-Legal and Patient Experience on extension 2123.

11.5 Court appointed deputies

Where a person lacks capacity the Court of Protection can make an order making a decision on their behalf. If for some reason this is not possible, the court may appoint a deputy to make a decision on behalf of the person who lacks capacity. Any decision made must be in the patient's best interests.

Any such appointment would only be made in difficult cases where there was no other way of settling the matter in the best interests of the person who lacks capacity. (It could therefore be helpful to know if there has been a history of family disputes).

If a court appointed deputy has been appointed, it is the deputy and not the health care professional who makes the treatment decision.

However, a deputy can not counter the decision made by an attorney appointed under an LPA made before the person lacks capacity.

A deputy cannot refuse consent to the provision of life saving treatment (this decision can only be made by the court). It is also important to note that the deputy can only act in accordance with the terms of his or her appointment. If these were not considered sufficient, application must be made back to the court.

Staff should ask to see a copy of the appointment setting out the terms for which the deputy has been appointed.

For further information, please seek advice from the Assistant Director of Medico-Legal and Patient Experience on extension 2123.

11.6 Independent Mental Capacity Advocates (IMCAs)

Where a person lacks capacity and where an NHS body is proposing 'serious medical treatment' and the patient has no-one to speak for them other than paid care staff, the MCA has imposed a duty on the NHS body to appoint an IMCA.

Serious medical treatment

The definition of this is set out in detail at section 10.42 of the MCA Code of Practice and is defined as:

"Treatment which involves giving new treatment, stopping treatment which has already started, or withholding treatment which could be offered in circumstances where:

- if a single treatment is proposed there is a fine balance between the likely benefits and the burdens to the patient and the risks involved
- a decision between the choice of treatments is finely balanced, or
- what is proposed is likely to have serious consequences for the patient."

'Serious consequences' are those which could have a serious impact on this particular patient, either due to the treatment or its wider implications. It would be difficult to specify all procedures which would fall into this category; some are listed in the Code of Practice. Ultimately, whether a treatment falls within this definition will depend on the particular circumstances and consequences for the patient concerned.

While an IMCA is to be consulted on what is best for the patient, there is no need for the IMCA to sign the consent form. IMCAs are not decision makers but are there to support and represent the patient in accordance with the MCA.

Other areas where IMCAs can help

If decisions are being made relating to adult protection or a care/accommodation review, statutory organisations may refer to IMCA (there is no duty) if they feel it would be of benefit to the person to have an IMCA to represent them.

The MCA gives IMCAs a right to access information about the patient, providing it is considered relevant information by the person holding the record.

Please see additional guidance available at www.dh.gov.uk/imca or www.cambridgeshire.gov/social/mental

Referrals for an IMCA are made to Speaking Up who have been commissioned by Cambridgeshire Local Authority to provide this service. The service is available weekdays 9am - 5pm.

For a referral to Speaking Up staff should contact either the Assistant Director of Medico-Legal and Patient Experience on extension 2123 or the

Assistant Director of Patient Experience and Public Engagement on extension 58105.

IMCA Referral Line: 0845 650 0081
email: imca@speakingup.org or www.speakingup.org

11.7 Involvement of family and others

The MCA states that healthcare professionals must, as far as is possible, consult other people if it is appropriate to do so, and take any such persons' views into account as to what would be in the best interests of the patient.

There is space on Form 4 for family members to sign the consent form to evidence that they have been consulted. If they choose not to do so, or are not available in person and hence are consulted over the telephone, it is recommended that this is recorded in the patient's notes, and noted on the form. It is not compulsory for family members or other persons to sign the form.

Clinicians should demonstrate in their record keeping that the final decision made has been based on all available evidence and has taken into account any conflicting views.

11.8 What if there is a problem?

For any problems arising in connection with any of the issues contained in this aspect of the policy, please contact the Assistant Director of Medico-Legal and Patient Experience on extension 2123.

12 Refusal of Consent

If the process of seeking consent is to be a meaningful one, refusal must be one of the patient's options. An adult patient with capacity is entitled to refuse any treatment, except in circumstances governed by the Mental Health Act 1983. The situation for children is more complex: see the Department of Health's *Seeking consent: working with children* for more detail. The following paragraphs apply primarily to adults.

If, after discussion of possible treatment options, a patient refuses all treatment, this fact should be clearly documented in their notes. If the patient has already signed a consent form, but then changes their mind, you (and where possible the patient) should note this on the form.

Where a patient has refused a particular intervention, you must ensure that you continue to provide any other appropriate care to which they have consented. You should also ensure that the patient realises they are free to change their mind and accept treatment if they later wish to do so. Where delay may affect their treatment choices, they should be advised accordingly.

If a patient consents to a particular procedure but refuses certain aspects of the intervention, you must explain to the patient the possible consequences of their partial refusal. If you genuinely believe that the procedure cannot be safely carried out under the patient's stipulated conditions, you are not obliged to perform it. You must, however, continue to provide any other appropriate care. Where another health professional believes that the treatment can be safely carried out under the conditions specified by the patient, you must on request be prepared to transfer the patient's care to that health professional.

Refusal of treatment by a child or young person

If a young person or Gillick competent child refuses potentially life saving treatment or treatment which would prevent severe permanent injury, it is possible such refusal could be overruled.

While court decisions made before the Human Rights Act 1998 (HRA) suggest that a parent can consent on behalf of their child, where the child refuses any such treatment this has not been tested post the HRA. It would therefore be prudent to seek immediate advice in such a case. For advice please contact the Assistant Director of Medico-Legal and Patient Experience on 2123.

If a life saving emergency arose where consultation with either a parent or the court was impossible, the courts have advised that doubt should be exercised in favour of the preservation of life.

Change of mind to a post mortem

Please refer to the section on [post mortem](#) above.

13 Advance decisions to refuse treatment

These were previously known as 'living wills or advance directives'. If a person has made a valid and applicable advance decision to refuse treatment, this has the same force as a contemporaneous decision to refuse treatment.

While this has been the rule of 'common law', this principle now has statutory effect following enactment of the MCA. For full details please refer to the Trust's policy [Advance Statements, Advance Decisions, and Lasting Powers of Attorney in relation to Future Medical Treatment](#). Details are also set out in Chapter 9 of the MCA Code of Practice but in summary the key elements are:

- the person must be 18 or over
- the person must have capacity to make the decision
- it must be clear which treatment(s) is/are being refused
- if this concerns life saving treatment, the advance decision must be in writing (either written by someone else or recorded in health care notes), signed and witnessed and must state clearly it applies even if life is at risk

- the advance decision can be withdrawn at any time by a person with capacity.

Except in circumstances governed by the Mental Health Act 1983, healthcare professionals **must** follow a valid and applicable advance decision, even if it will lead to death. If they do not, the Reference Guide advises that they could face criminal prosecution or liability. If a healthcare professional disagrees in principle with a decision to refuse life-saving treatment, care should be transferred to another health care professional. The Reference Guide advises that where a doctor is unable to carry out the wishes of a patient, their duty is to find another doctor who will do so⁴. Clinicians are also advised to follow the advice of their professional organisations (such as the British Medical Association). For a more detailed explanation and guidance on how to proceed, staff must refer to the full policy as indicated above.

It is imperative that health professionals follow the MCA Code of Practice. If there is genuine doubt or disagreement about an advance decision's existence, validity or applicability, reference should be made to the Court of Protection. For advice on this, please contact the Assistant Director of Medico-Legal and Patient Experience on 2123.

14 Further information, other languages & formats

14.1 Patient Safety contacts

Assistant Director of Medico-Legal and Patient Experience on extension 2123
Assistant Director of Risk & Patient Safety on extension 3880
On call manager (via hospital contact centre).

14.2 Patient Advice and Liaison Service (PALS) extension 2756 or 57257

The PALS Information Centre aims to help patients and staff with advice and information about health, care and benefit issues. It can also be accessed online: www.addenbrookes.org.uk/pals. Staff can help patients access further information sources i.e. NHS Direct online and the National Electronic Library for Health. PALS offers advice and help for people with disabilities and links to specialist advice, see www.addenbrookes.org.uk/advice/links/disability.html for local independent advocacy groups and other disability contact groups.

14.3 Patient Information

Please refer to the [patient information policy](#) for guidance on developing patient information produced by the Trust or contact Patient Information on extension 2032 for advice. **Media Studio** is available on extension 2417.

⁴ Reference Guide, paragraph 11 at page 7

Patient information and consent forms can be accessed via the internet by patients and members of the public.

http://www.addenbrookes.org.uk/patient_visitors/information_leaflets/information_leaflets.htm

<http://www.addenbrookes.org.uk/consent/index.html>

If members of the public do not have internet access at home, there are public internet access stations in various areas of the hospital for their use.

The Visual Impairment Officer in Ophthalmology can also give advice where patients cannot access printed information easily.

14.4 Information in other languages

The Trust is committed to ensuring that patients whose first language is not English receive the information they need and are able to communicate appropriately with healthcare staff. (please see [section 11.3](#) above on the use of the hospital's communication book with previously translated common sentences). It is not appropriate to use children to interpret for family members who do not speak English.

Staff must ensure that, where possible, patients who do not clearly understand English are given the services of a reliable interpreter. The interpreter must sign the relevant section of the consent form to say they have interpreted the information to the patient to the best of their ability and in a way in which they believe has been understood.

The Trust has organised telephone interpreting services through [language line](#). If language line is used and the interpreter is not present, please obtain a verbal confirmation and record this on the consent form. The interpreter must understand and respect the need for confidentiality. [Face to face interpreters](#) are available from CINTRA (Cambridge Interpreting and Translation Agency).

CINTRA leaflets can be found throughout the Trust. Further information can be accessed by visiting <http://www.addenbrookes.org.uk/serv/nonclin/interpret1.html> or telephone: 01223 346870.

In addition, the standard Department of Health consent forms are also available in a number of different languages <http://www.doh.gov.uk>.

Please consider whether patients need information in an audio or large print format in which case contact the patient information team for assistance.

14.5 Department of Health

In addition to the Reference Guide, the MCA Code of Practice and the Office of the Public Guardian, the Department of Health has a great deal of useful information on its website. Health professionals must also be aware of any guidance on consent issued by their own regulatory bodies.

<http://www.dh.gov.uk>

14.6 Human Tissue Authority

The Human Tissue Authority has produced both a code of practice on consent and post mortem examination, which is available at the following link: http://www.hta.gov.uk/guidance/codes_of_practice.cfm The HTA has also produced a code of practice for research.

The **Tissue Bank Manager** is available on extension 6099. The Cambridge **Local Research Ethics Committee** can be contacted through their administrator on extension 3983.

15 Monitoring compliance with and the effectiveness of this document

Standard 4.3. of the 2010-11 NHS Litigation Authority Risk Management Standards sets out minimum requirements for a consent policy which includes the following:

- a) the process for obtaining consent
- b) the process for recording consent
- c) the process for identifying staff who are not capable of performing the procedure but are authorised to obtain consent for that procedure
- d) generic training on the consent process
- e) the process for the delivery of procedure specific training on consent, for staff to whom the consent process is delegated and who are not capable of performing the procedure
- f) the process for monitoring compliance with the above.

This consent policy will be monitored as set out below.

15.1 The annual consent audit and patient survey

The annual consent audit is undertaken by the Programme Manager for Patient Information and reviews over 250 randomly selected patient notes for a range of elective procedures undertaken during the preceding 12 months. The audit includes analysis of the following variables:

- accuracy of completion of the consent form
- application of the 'procedure completed' stamp
- evidence that written patient information about the procedure has been provided to the patient

- the grade of staff seeking consent and whether or not they are capable of performing the procedure
- if the person who has obtained consent is not capable of performing the procedure in question, whether they have they undergone the requisite general and consent competency training (by examination of training tracker records and the training recorded for that individual on the electronic staff register)

Following completion of the audit, a patient survey is sent to those patients (aged over 18) whose notes were audited. The patient survey asks patients for their perceptions of the consent process by inviting them to provide feedback on aspects of the process of giving consent including whether:

- the risks, benefits and alternatives of the procedure were explained
- the patient had an opportunity to make their wishes known
- the patient was asked to re-confirm consent and if so, whether patients found this useful.

Once the results have been collated, the Programme Manager for Patient Information will prepare an audit report with the audit and survey results and recommendations to be distributed to:

- the deputy medical directors
- all divisional directors
- the Patient Safety Executive (PSE)
- the Advisory Group for Patient Information
- the Trust's compliance manager

The PSE are responsible for monitoring implementation of any recommendations arising out of the report. Any areas identified for action will be communicated to the relevant clinical director concerned, with escalation to the divisional director and ultimately to the medical director if required.

The results of the consent audit will also be submitted to the Head of Performance Intelligence for inclusion on the strategic dashboard as part of the ongoing review of the Trust's objectives.

15.2 Annual review of the Consent Competency Register

A copy of the relevant entry on the Consent Competency Register will be sent annually to all clinical departments and also to all lead divisional nurses to ensure accuracy of the central register.

Clinical Directors and lead divisional nurses will be asked:

- a) to confirm whether consent is delegated/not delegated in that department,
- b) which groups of staff may conduct consent training
- c) to which groups of staff consent taking may be delegated

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Where consent is delegated in that department, details should be provided of the procedures for which consent may be delegated and the names of the staff able to provide that training.

Responses will be entered onto the electronic register maintained by the patient information team and any hard copy responses will also be kept by the administrator for patient information. A copy of the updated register will be sent annually to medical staffing.

15.3 Junior Doctors' consent training

Where the consent audit highlights individuals who have taken consent but are not yet capable of performing the procedure concerned (ie they are below SpR level) the patient information team will consult training tracker to ensure that individual has passed the general consent module and also the electronic staff register to check for the specialty specific consent training.

Where no training records are available or there is no entry noted on the electronic staff register, medical staffing will be informed and this will be followed up by medical staffing with the relevant clinical director involved, and where necessary will be escalated to the relevant divisional director.

16 Associated documents

- the Trust's Mental Capacity Act [assessment form](#)
- [consent competency training packages](#) for delegated consent
- the Trust's generic [consent forms](#)
- Trust's [Photographic Policy and Procedure](#)
- the Trust's policy on [vulnerable adults](#)
- the Trust's policy [Advance Statements, Advance Decisions, and Lasting Powers of Attorney in relation to Future Medical Treatment](#)

Equality and diversity statement

This document complies with the Cambridge University Hospitals NHS Foundation Trust service equality and diversity statement.

Disclaimer

It is **your** responsibility to check against the electronic library that this printed out copy is the most recent issue of this document.

Document management

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Appendix 1 People with parental responsibility

- The child's mother
- The child's father, if he was married to the mother at the time of the birth
- Unmarried fathers will depend on whether or not the child was born after 1 December 2003:
 - For children born **before 1 December 2003**, unmarried fathers will have parental responsibility if they:
 - marry the mother of their child or obtain a parental responsibility order from the court
 - register a parental responsibility order with the court or by an application to the court
 - For children **after 1 December 2003**, unmarried fathers will have parental responsibility if they:
 - register the birth jointly with the mother (automatic parental responsibility)
 - re-register the birth if they are the natural father
 - marry the mother of the child or obtain a parental responsibility order from the court
 - register with the court for parental responsibility
- The child's legally appointed guardian
- A person in whose favour the court has made a residence order
- A local authority designated in a care order or with an emergency protection order

Notes

More than one person may have parental responsibility at the same time. Foster parents do not automatically have parental responsibility unless they fall within a category as above. If a child is adopted, both parents have parental responsibility.