Policy & Guidelines for Consent to Examination or Treatment

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Disclaimer

Since every patient's history is different, and even the most exhaustive sources of information cannot cover every possible eventuality, you should be aware that all information is provided in this document on the basis that the healthcare professionals responsible for patient care will retain full and sole responsibility for decisions relating to patient care; the document is intended to supplement, not substitute for, the expertise and judgment of physicians, pharmacists or other healthcare professionals and should not be taken as an indication of suitability of a particular treatment for a particular individual.

The ultimate responsibility for the use of the policy, dosage of drugs and correct following of instructions as well as the interpretation of the published material **lies solely with you** as the medical practitioner.

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Key messages

This policy covers:

- How to obtain informed consent
- The validity of consent
- The importance of mental capacity in relation to consent
- Exceptions to the principles of consent
- The legal position in relation to consent

1.0 Introduction

1.1 Policy Statement

Since this policy was first introduced in 2002, there has been new legislation affecting the treatment of people who lack capacity to make some decisions for themselves, and this came into force in October 2007.

The General Medical Council published new guidance on consent in 2008. The Department of Health issued a revised model policy for Trusts to adopt in 2009 in defining the law for consent to examination or treatment. This policy should be read in conjunction with the Trust's Mental Capacity Act policy and Interpretation, translation and Accessing Information to meet Individual needs Policy.

1.2 Objectives

Patients have a fundamental legal and ethical right to determine what happens to their own bodies. Valid consent to treatment is therefore absolutely central in all forms of healthcare, from providing personal care to undertaking major surgery. Seeking consent is also a matter of common courtesy between health professionals and patients.

2.0 Scope of document

This policy sets out the standards and procedures in the Trust to enable health professionals to comply with the guidance. While this document is primarily concerned with healthcare, social care colleagues should also be aware of their obligations to obtain consent before providing certain forms of social care.

This document includes 3 sets of guidelines given in section - 6:

- General guidance on obtaining consent;
- Written consent, recording consent and written information; and
- Seeking consent in specific circumstances, including anaesthesia, emergencies, tissue collection, photography, robotic surgery, radiographic procedure under anaesthetic and research.

3.0 Roles and responsibilities

Role	Responsibility
Clinical lead for the service in discussion with the Medical Director/Clinical Directors	Deciding which procedures need formal, written consent and which need verbal consent
The person carrying out the intervention	Obtaining and recording consent, including provision of supporting information. This should include risks and benefits of intended intervention. Ensuring that when they require colleagues to seek consent on their behalf, they are confident that the colleague is competent to do so
A person obtaining consent on behalf of another clinician	To work within their own competence and not to agree to perform tasks which exceed that competence

3.1 Training

No member of staff is authorised to obtain consent unless they have been appropriately trained. Consent can only be undertaken by the following:

- Staff who are specifically trained to do so e.g. Surgical Assistants
- Clinician who is undertaking the procedure
- Clinicians who can/usually perform the procedure on the consent form. This will be at Registrar and above level

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4.0 Implementation and dissemination of document

This policy will be available on workspace the local intranet. When any policy changes are approved the author will ensure that the information is cascaded to those groups of staff that will use the policy. Trust induction and risk management training highlights the need for all staff to take responsibility for making themselves aware and keeping updated with those policies that relate to their area of work. This is implemented at local induction.

5.0 Definition and explanation of term

5.1 Consent

"Consent" in relation to this policy is a patient's agreement for a health professional to provide care and/or treatment. Patients may indicate consent non-verbally (for example by presenting their arm for their pulse to be taken), orally, or in writing. For the consent to be valid, the patient must:

- be competent [have capacity] to take the particular decision;
- have received sufficient understandable information to take it; and
- not be acting under duress.

The context of 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 provide advice on the risks and benefits of each (and of doing nothing) and will be available to assist 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 attempt come to an agreement on the best way forward, based on the patient's values and preferences and the health professional's clinical knowledge. Where the patient has capacity, their decision must be respected in full, even if it goes against the medical advice of the health professional.

It used to be the case that if an adult patient lacked capacity, no-one else could give consent on their behalf, though treatment could be given in their best interests, if it had not been refused in a valid and applicable advance decision. This is no longer the case and this is dealt with in section 5.2 below.

5.2 Mental Capacity

The Mental Capacity Act (MCA) 2005 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.

The MCA enshrines 5 key principles in statute, underpinning the mechanism by which capacity is to be assessed, and best interests determined. Subject to compliance with the MCA, decisions may now be taken on behalf of an adult lacking capacity by someone appointed under a Lasting Power of Attorney or by a Court of Law.

Those with a Health and Welfare Lasting Power of Attorney can consent for medical treatment on behalf of the incapacitated adult as long as the power allows for such a decision to be made. However, those in possession of a Property and Financial Lasting Power of Attorney cannot consent for medical treatment.

5 key principles

1. A person must be assumed to have capacity unless it is established that he/she lacks capacity."
2. People must be helped to make decisions "A person is not to be treated as unable to make a decision unless all practicable steps to help him/her to do so have been taken without success."
3. Unwise decisions do not necessarily mean lack of capacity "A person is not to be treated as unable to make a decision merely because he/she makes an unwise decision."
4. Decisions must be taken in the person's best interests "An act done, or decision made under this Act for or on behalf of a person who lacks capacity must be done, or made, in his/her best interests."
5. Decisions must be as least restrictive of freedom as possible "Before the act is done, or the decision is made, regard must be had to whether the purpose for which it is needed can be as effectively achieved in a way that is less restrictive of the person's rights and freedom of action."

5.3 Age and capacity

The MCA does not apply to children under 16, and nobody under 18 can make a Lasting Power of Attorney, or an Advance Decision. If a child under 16 lacks capacity, (either temporarily or permanently), consent can, as before, be given by someone with 'parental responsibility' for the child. If a young person aged 16-18 lacks capacity to consent to treatment, then s/he can be treated, provided that the MCA is complied with; essentially, acting in best interests and assessing in consultation with family/carers where possible and appropriate.

Children under 16 can consent to medical treatment if they understand what is being proposed. It is up to the doctor to decide whether the child has the maturity and intelligence to fully understand the nature of the treatment, the options, the risks involved and the benefits. This is referred to as being Fraser Competent.

A child who has such understanding is considered Gillick competent (or Fraser competent). The parents cannot overrule the child's consent when they are judged to be Gillick competent.

As before, a person aged 16 or more is presumed to be competent to give consent for themselves, unless it is demonstrated that he/she lacks capacity.

The courts have stated that if a child under the age of 16 has "sufficient understanding and intelligence to enable him or her to understand fully what is proposed", then s/he will be competent to give consent for himself or herself.

A competent child is legally entitled to withhold consent to treatment. However, even though the young person may be considered to be Gillick competent, there are some situations where their refusal can be overridden by those with parental responsibility. If the treating doctor believes that the withholding of consent may be detrimental to the patient's wellbeing, legal advice may be required. It may be necessary for a court to determine whether treatment can be given against the wishes of the competent child.

Patients aged 16-18 can withhold consent to treatment, but this can be overruled in exceptional circumstances if it is considered to be in their best interests, either by someone with parental responsibility or by the courts.

6.0 Guidelines

This section includes:

6.1 General guidance on obtaining consent
6.2 Written consent, recording consent and written information
6.3 Seeking consent in specific circumstances, including anaesthesia, emergencies tissue collection, photography, radiographic procedure under anaesthetic and research

6.1 General guidance on obtaining consent

To give valid consent the person needs to understand the nature and purpose of the procedure. Any misinterpretation of these elements will invalidate consent.

To take consent:

- Information should be in clear terms
- There must be a dialogue, and this must be recorded and copied to the patient
- Staff must "avoid" bombarding the patient with technical information which he/she cannot reasonably be expected to "grasp"

For significant procedures, it is essential for health professionals to document clearly both a patient's agreement or disagreement to the intervention 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 notes if necessary (to document discussions held and advice given regarding the treatment), or through documenting in the patient's notes that they have given oral consent.

The person undertaking consent has a duty to take **reasonable care** to ensure that the patient is aware of **any material risks** involved in any recommended treatment, and of any reasonable alternatives or variant treatments.
The **test of materiality** is whether, in the circumstances of the particular case, **a reasonable person** in the patient's position would be likely to attach **significance to the risk**, or the doctor is or should **reasonably be aware** that this **particular patient** would be likely to attach significance to it.

There are three exceptions to the duty to inform:

- If a patient tells the doctor he/she would prefer not to know the risks
- When the doctor reasonably considers that disclosure of a risk would be seriously detrimental to the patient's health
- In circumstances of necessity for example in an emergency where a patient requires treatment urgently but is unconscious or unable to make a decision

6.1.1 When should consent be sought?

Before you examine, treat or care for competent adults, children or young person you must obtain their consent.

It is best practice that consent is undertaken in the Outpatient setting rather than on the day of surgery for all elective procedures.

Adults are always presumed to be competent unless demonstrated otherwise. If you have doubts about their competence, the question to ask is: "can the patient understand and weigh up the information needed to make this decision and communicate the same?" Unexpected decisions do not prove the patient is incompetent, but may indicate a need for further assessment, information or explanation.

Patients may be competent to make some health care decisions, even if they are not competent to make others.

When a patient formally gives their consent to a particular intervention, this is only the **endpoint** of the consent process. It is helpful to see the whole process of information provision, discussion and decision-making as 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 treatment.

Patients can change their minds and withdraw their consent at any time. If there is any doubt you should always check that the patient still consents to you caring for or treating them. Where consent is withdrawn this must also be clearly documented in the medical notes.

The same principles apply when treating a child. Younger children who understand fully what is involved in the procedure, and are competent, can give consent (although their parents will ideally be involved.) In some exceptional cases someone with parental responsibility must give consent on the child's behalf, unless they cannot be reached in an emergency. If a competent child consents to treatment, a parent **cannot** over-ride that consent. Legally a parent can consent if a competent child refuses, but it is likely that taking such a serious step will be rare.
Valid consent of young persons aged 16-18 years cannot be overridden by those with parental responsibility. However, if the decision to override by the parents is considered to not be in the best interests of the young person then that decision can be overridden in certain circumstances by their parents or guardians or by the court and this must be decided on a case by case basis and legal advice should be sought where necessary.

6.1.2 Who is responsible for seeking consent?

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. Information may be provided to the patient by another health professional, provided s/he is competent to do so, through having undertaken procedure-specific training. The health professional who has provided information to the patient should then sign the consent form.

Where procedures are being requested by one clinical specialty but being undertaken by another e.g. Interventional radiology, the requesting team must ensure that all relevant information is on the procedure request card to enable the clinical undertaking the procedure is appropriately informed of the patient's clinical history and presenting concerns.

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 health professional responsible for the procedure. 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 order to ensure that informed consent is properly obtained.

6.1.3 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.

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 enough 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.

6.1.4 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 on the ward 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: the first being the provision of information, discussion of options and initial (oral) decision, and the second being confirmation that the patient still wants to go ahead. The consent form should be used as a means of documenting the information stage(s), as well as the confirmation stage.

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 and should have received a copy of the page documenting the decision-making process. They may be invited to sign the form, confirming that they wish treatment to go ahead, at any appropriate point before the procedure: in out-patients, at a pre-admission clinic, or when they arrive for treatment. If a form is signed before patient

arrives for treatment, however, a member of the healthcare team **must** check with the patient at this point whether they have any further concerns and whether their condition has changed. This is particularly important where there has been a significant lapse of time between the form being signed and the procedure[1]. 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.

6.1.5 Consent sharing

Where the Community Matrons are managing patient care and require information from another healthcare provider, patients must be asked to sign a consent statement form (appendix 13). This will authorise the Matrons to request information from the hospital and allow them to best manage patients' conditions.

6.2 Written Consent, Recording Consent and Written Information

Consent is often wrongly equated with a patient's signature on a consent form. A signature on a form is *evidence* that the patient has given consent but 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. Patients may, if they wish, withdraw consent after they have signed a form: the signature is evidence of the process of consent-giving, not a binding contract. What is essential is that the crucial elements of the discussion with the patient are documented in the medical notes, and copied to the patient

It is rarely a legal requirement to seek written consent,[2] but it is good practice to do so 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;

[1] The period of 72 hours is suggested as a general 'rule of thumb'; being a period over which there may be some risk that (1) the patient's underlying condition could have altered; and/or (2) s/he may need some reminder of the information upon which his/her consent was originally based

[2] The Mental Health Act 1983 and the Human Fertilisation and Embryology Act 1990 require written consent in certain circumstances.

- there may be significant consequences for the patient's employment, social or personal life; and

- the treatment is part of a project or programme of research approved by the Trust.

Completed Consent Forms must be kept in the patient record. If the consent form is completed in an outpatient clinic it must be filed into the patient's paperlite folder. Medical Records will scan it onto the Electronic Document Management (EDM) System and retain the original in anticipation of the patient's admission. Prior to the admission Medical Records will provide a patient folder to the ward containing the original consent form. Any changes to a form, made after the form has been signed by the patient, should be initialed and dated by both patient and health professional and filed in the patient's paperlite folder along with the original consent form. Once the patient has been discharged the consent form will be scanned onto EDM along with the other paperwork for the admission and after quality assurance has taken place the paper copy will be destroyed.

It is also good practice to record the discussions with the patient that forms part of their medical records.

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 helpful to do so. A full note of the consent and concerns should be written within the patient records.

Where it would be good practice to obtain written consent to the particular treatment or intervention proposed, and the patient has capacity to give or withhold that consent, then a 'Consent to Treatment' Form should be completed. The standard consent forms are listed in Appendix 2 and are available from Purchasing and Supplies Department. There are four versions of the Standard Consent Form: **Form 1** for adults or competent children; **Form 2** for parental consent for a child or young person; and **Form 3** for cases where it is envisaged that the patient will remain alert throughout the procedure and no anaesthetist will be involved in their care. The use of form 3 is optional but may be thought more appropriate than form 1 in situations where patients do not need to be made aware of issues surrounding general or regional anaesthesia and do not need to make any decisions in advance about additional procedures because they will be in a position to make any such decisions at the time if necessary. **Form 4** is for patients who for various reasons cannot give their own consent

6.2.1 Completing consent forms

If the patient signs the form in advance of the procedure (for example in out-patients 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. It will be appropriate for any member of the healthcare team (for example a nurse admitting the patient for an elective procedure) to provide the second signature, as long as they have access to appropriate colleagues to answer questions, they cannot handle themselves.

Clinical teams should give consideration as to what procedures are in place to ensure that the health professionals 'confirming' the patient's consent genuinely have access to appropriate colleagues, where they personally may not be able to answer any remaining questions.

If any questions cannot be answered immediately, the health professional 'confirming' the patient's consent should note any outstanding questions and refer them to the admitting doctor/consultant.

The questions should be recorded on the consent form (if there is room) and/or in the patient's notes, together with the identity of the health professional to whom they have been referred. As part of the clerking procedure, the admitting doctor should record his/her response, and whether the patient is happy to confirm his/her consent.

6.2.2 Provision of information

The provision of information is central to the consent process. Before patients can come to a decision about treatment, they need comprehensible information about their condition and about possible treatments/investigations, alternative treatment options and their risks and benefits (including the risks/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. These discussions and any written information given should be documented and filed within the patients' medical records

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. Where the patient makes clear (verbally or non-verbally) that they do not wish to be given this level of information, this should be documented.

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, are aware of their own knowledge limitations and are subject to audit.

If any clinical team wishes that information be provided by health professionals who do not themselves carry out the procedure, they should refer to their head of department for further guidance as to the procedure-specific training required. Any health professional providing information to the patient must demonstrate a thorough understanding of the procedure, and of its risks and benefits. They must be in a position to address any question that might reasonably be anticipated.

6.2.3 Access to more detailed or specialist information

Patients may sometimes request more detailed information about their condition or about a proposed treatment. Information leaflets are available for most procedures and should be routinely provided where available and documented as having been given in the patients' medical records including eCare:

- When the patient sees the Consultant or a member of his/her team
- By the Pre-Assessment Team as part of the Care Pathway to ensure the patient has received all the information they need to make an informed decision on their care or treatment

Patients can obtain **additional information** from Healthcare Professionals in between appointments by telephoning the Pre-Assessment Team member who undertook their pre assessment using the bleep number provided at the time of the pre-assessment appointment and again this request for further information must be recorded within the patient's medical records.

6.2.4 Provision for patients who may have difficulties with understanding

This Trust is committed to ensuring that patients who may have difficulties understanding information (e.g. language, deafness etc.) receive the information they need and are able to communicate appropriately with healthcare staff. It is not appropriate to use children to interpret for family members who do not speak English. **Please refer to the Trust's interpretation, translation and accessing information to meet induvial needs Policy.**

6.2.5 Gynaecology specific consent

The Royal College of Gynaecology consent guidance in relation to laparoscopic management of tubal pregnancy states that the patient should be consented for & the consent form should read "Laparoscopic salpingectomy or salpingotomy after confirmation of tubal ectopic pregnancy". Additional information in relation to the intended benefits of the procedure and the associated risks is further required.

6.2.6 World Health Organisation (WHO) safety checks in relation to consent

The Theatre operational policy requires the patient to confirm his/her signature on the consent form and consent is further verified as part of the WHO safety checklist at the 'Sign in' and Time Out' stages.

WHO debrief takes place prior to the procedure is a stage intended to insure consent is correct.

6.3 Seeking Consent in Specific Circumstances

6.3.1 Anaesthesia

Where an anaesthetist is involved in a patient's care, it is their responsibility (not that of the clinician carrying out the procedure) to seek consent for anaesthesia, having discussed the benefits and risks. However, in elective treatment it is not acceptable for the patient to receive no 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 out-patients 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 notes 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.

6.3.2 Emergencies where the patient is competent.

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 it may often be appropriate to use the patient's notes to document any discussion and the patient's consent, rather than using a form. The urgency of the patient's situation may limit the quantity of information that they can be given but should not affect its quality.

6.3.3 Tissue

The Human Tissue Act 2004 sets out a firm legislative framework for 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.

The Human Tissue Act establishes the Human Tissue Authority as the regulatory body for all matters concerning the removal, storage, use and disposal of human tissue (excluding gametes and embryos) for schedules purposes.

The Human Tissue Act makes consent the fundamental principle in treatment and research involving tissue. The absence of refusal is not seen as the giving of consent under the Act. Explicit consent is not necessary for public health surveillance using the unlinked anonymous method, but in seeking consent as above, the Trust requires that patients understand that they can decline (or limit) their consent to certain uses of the tissue.

This Trust requires that patients should be given the opportunity to confirm whether or not they agree that tissue taken from them during surgery or other procedures may be used for education or research purposes. A patient should also be given the opportunity to state if they object to any particular uses or use of the particular tissues. A patient's agreement or objection should be recorded on the consent form and transcribed onto any request form submitted to laboratories.

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.

6.3.4 Organs Donation

From spring 2020, organ donation in England will move to an 'opt out' system. You may also hear it referred to as 'Max and Keira's Law'.

This means that all adults in England will be considered to have agreed to be an organ donor when they die unless they have recorded a decision not to donate or are in one of the excluded groups.

You still have a choice if you want to be an organ donor or not when you die. Get the facts about organ donation to help you decide.
The law is being changed to help save and improve more lives. Every day across the UK, someone dies waiting for a transplant

The NHS is asking everyone to:

1. Record your organ donation decision on the NHS Organ Donor Register
2. Tell your family and friends what you have decided

The opt out system in England will come into effect from spring 2020. The law around organ donation in England will remain 'opt in' until this time.

These changes will affect all adults in England unless they have recorded a decision not to donate or are in one of the following excluded groups:

- Those under the age of 18
- People who lack the mental capacity to understand the new arrangements and take the necessary action
- Visitors to England, and those not living here voluntarily
- People who have lived in England for less than 12 months before their death

6.3.5 Clinical photography and conventional or digital video recordings

Photographic and video recordings made for clinical purposes form part of a patient's record. Although consent to certain recordings, such as X-rays, is implicit in the patient's consent to the procedure, health professionals should always ensure that they make clear in advance if any photographic or video recording will result from that procedure.

Whilst photography and video recordings may not be physically invasive, nor are they generally thought to carry significant physical risk to the patient, it should be remembered that they can be invasive of the patient's privacy, and there may be a risk that their subsequent use could adversely affect the patient's employment, social or personal life (e.g. through inappropriate publication). As such, and in accordance with the principles of section 5.2.1 above, it is good practice generally to consider the need to obtain express written consent.

In particular, photographic and video recordings which are made for treating or assessing a patient must not be used for any purpose other than the patient's care or the audit of that care, without the express written consent of the patient or a person with parental responsibility for the patient. The one exception to this principle is set out below. If you wish to use such a recording for education, publication or research purposes, you must seek consent in writing, ensuring that the person giving consent is fully aware of the possible uses of the material. In particular, the person must be made aware that you may not be able to control future use of the material once it has been placed in the public domain *e.g.* on a website. If a child is not willing for a recording to be used, you must not use it, even if a person with parental responsibility consents.

Photographic and video recordings, made for treating or assessing a patient and from which there is no possibility that the patient might be recognised, may be used within the clinical setting for education or research purposes without express consent from the patient, as long as this policy is well publicised. However, express consent must be sought for any form of publication.

If staff wish to make a photographic or video recording of a patient specifically for education, publication or research purposes, you must first seek their written consent (or where appropriate that of a person with parental responsibility) to make the recording, and then seek their consent to use it. Patients must know that they are free to stop the recording at any time and that they are entitled to view it if they wish, before deciding whether to give consent to its use. If the patient decides that they are not happy for any recording to be used, it must be destroyed. As with recordings made with therapeutic intent, patients must receive full information on the possible future uses of the recording, including the fact that it may not be possible to withdraw it once it is in the public domain.

The situation may sometimes arise where you wish to make a recording specifically for education, publication or research purposes, but the patient is temporarily unable to give or withhold consent because, for example, they are unconscious. In such cases, you may make such a recording, but you must seek consent as soon as the patient regains capacity. This Trust advises that the patient's consent be confirmed expressly in writing. You must not use the recording until you have received consent for its use, 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, you should seek the agreement of someone close to the patient. The Trust advises that this be recorded in writing. You must not make any use of the recording which

might be against the interests of the patient. You should also not make, or use, any such recording if the purpose of the recording could equally well be met by recording patients who are able to give or withhold consent.

6.3.6 Consent for radiographic procedure under anaesthetic

Whilst verbal consent is generally sufficient to proceed with a radiographic procedure, the Trust is required to have procedures in place for making enquiries of females of child-bearing age to establish whether the individual is or may be pregnant[3].

Since such enquiries cannot be made of a patient under anaesthetic, if a female patient aged 12-55 is likely to require an X-ray during surgery, the health professional that is obtaining consent should make such enquiry before surgery and should document the patient's answer on the consent form.

6.3.7 Robotic Surgery

It is the responsibility of the surgeon performing the procedure to initiate the consent discussion. Key areas that must be covered in each discussion include:

- The surgeon's personal experience and position on the learning curve.
- The additional risks/benefits of robotic surgery.

Although no know "additional" risks to robotic surgery have been reported, it is believed that in the early stages of learning curve, operative times may be increased which should be conveyed to the patient until surgeon competence is attained.

The benefits to RAS should be procedure specific. Due to the innovative nature, the data is often conflicting hence it should be stipulated that this is "perceived" benefit if appropriate. Generic benefits such as improved ergonomics, vision etc can be discussed.

- The alternatives available:

Conventional laparoscopic or open surgery should be offered as an alternative.

- The potential for video recording of the procedure (on specified cases)

The consent process for any robotic assisted procedure must begin in the outpatient department. Patients will be required to sign the relevant consent forms in clinic to allow theatre planning, but it must be stressed that patients are free to change their mind. Patients are to be provided with the approved Patient Information Leaflet for review during a "cooling-off" period prior to surgery. On the day of surgery, the "confirmation of consent" section of the Trust consent form must then be completed, or a separate consent form completed if the patient has then opted for standard operative approaches instead.

[3] Ionising Radiation (Medical Exposure) Regulations 2000

6.3.8 Consent in research

All the principles and practices for:

- Gaining informed consent;
- Giving information in writing; and
- Withdrawing/withholding consent

are the same as for all clinical procedures. Additionally, the consent form, patient information and process for gaining consent should be written into the research protocol and approved by an NHS Research Ethics Committee. Please refer to the Trust's Research Governance Approval Policies on the R&D website for details.

For information on research and patients who lack capacity to give consent, please refer to the Mental Capacity Act.

The Mental Capacity Act does not apply to clinical trials of medicinal products; if a patient does not have the capacity to consent to participation in a clinical trial, please refer to guidance given in the Medicines for Human Use (Clinical Trials) Regulations 2004.

6.3.9 Consent for blood transfusion

Patients should be informed of their need for transfusion and the risks involved. The NHSBT patient information leaflet 'Receiving a blood Transfusion' should be given to the patient prior to the transfusion.
Patient Consent for Blood Transfusion (2020) SaBTO (Advisory Committee for the Safety of Blood Tissues and Organs) recommends that informed and valid consent for transfusion is completed for all patients who will likely, or definitely, receive a transfusion. These recommendations also apply to where transfusion might occur during a procedure where the patient is incapacitated, for example, where blood is routinely requested prior to surgery or where a 'group and save' or 'cross-match' sample is taken pre-procedure. Such shared decision-making discussions should be documented in the patient's clinical record.
All patients who receive a transfusion need to be informed that they have received a transfusion and details of any adverse events associated with the transfusion must be included in their hospital discharge summary to ensure both the patient and their family are aware.
Where consent is not possible, e.g. in emergency situations, clinical judgment must be used. If patient/guardian refuses to consent to transfusion; the matter should be referred to a senior doctor for advice and trust policy 'Treatment of patients refusing blood and blood components' referred to.
At MKUH document PATH-FM-2 'Transfusion Prescription and Administration Record' has a 'Consent to Transfusion' section to be completed by the prescribing Clinician and the discussion must be documented in the patient's clinical record.

Further information:
https://www.gov.uk/government/publications/blood-transfusion-patient-consent

7.0 Procedures to follow when patients lack capacity to give or withhold consent

See the Mental Capacity Act Deprivation of Liberty Policy for further information

7.1 General Principles

7.1.1. The Mental Capacity Act 2005 came fully into force in October 2007 and applies in England and Wales to everyone who works in health and social care and is involved in the care, treatment or support of people over 16 years of age who may lack capacity to make decisions for themselves. It is largely based on previous common law and creates a single, coherent framework for decision-making, including decisions about treatment. Detailed guidance is provided in the MCA 2005 Code of Practice (2007), which has statutory force. The Act imposes a duty on health professionals (and other healthcare staff) to have regard to the Code of Practice.

7.1.2 Under English law, no one is able to give consent to the examination or treatment of an adult who lacks the capacity to give consent for themselves, unless they have been authorised to do so under a Lasting Power of Attorney or they have the authority to make treatment decisions as a court appointed deputy. Therefore, in most cases, parents, relatives or members of the healthcare team cannot consent on behalf of such an adult. However, the Mental Capacity Act sets out the circumstances in which it will be lawful to carry out such examinations or treatment.

7.1.3 In general, the refusal to an intervention made by a person when they had capacity cannot be overridden if the advance decision is valid and applicable to the situation. There are certain statutory exceptions to this principle, including treatment for mental disorder under the Mental Health Act 1983. In order to be valid and applicable an advance decision to refuse treatment must:

a) state precisely what treatment is to be refused – a statement giving a general desire not to be treated is not enough;

b) may set out the circumstances when the refusal should apply – it is helpful to include as much detail as possible;

c) will only apply at a time when the person lacks capacity to consent to or refuse the specific treatment.

7.1.4 In order to be a valid and applicable advance decision regarding life sustaining medical treatment then the advance decision should:

a) Be put in writing and if th patient is unable to write, someone else should write the advance decision down for them.

b) The patient must have signed the advance decision and if they are unable to sign they can direct someone to sign on their behalf in their presence.

c) The patient making the decision must sign in the presence of a witness to the signature. The witness must then sign the document in the presence of the person making the advance decision. If the person making the advance decision is unable to sign, the witness can witness them directing someone else to sign on their behalf.

d) Must include a clear, specific written statement from the patient making the advance decision that specifies that the advance decision is to apply to the specific treatment even if their life is at risk.

7.1.5 The legal requirements of the Mental Capacity Act are underpinned by five statutory principles. One of these key principles is that any act done for, or any decision made on behalf of, a person who lacks capacity must be done, or made, in that person's best interests. This principle applies to health professionals as it does to anyone working with and caring for a person who lacks capacity. The Act also creates a new offence of ill treatment or willful neglect of someone who lacks capacity by someone with responsibility for their care or with decision-making powers.

7.1.6 The Mental Capacity Act provides healthcare professionals with protection from civil and criminal legal liability for acts or decisions made in the best interests of the person who lacks capacity. The Act makes it clear that when determining what is in a person's best interests a healthcare professional must not make assumptions about someone's best interests merely on the basis of the person's age or appearance, condition or any aspect of their behaviour.

7.1.7 The Act requires that a healthcare professional **must** consider all the relevant circumstances relating to the decision in question. These are described as factors that the healthcare professional is aware of and which are reasonable to take into account.

7.1.8 In considering the relevant circumstances, the Act rules that the healthcare professionals **must** take the following steps:

- Consider whether the person is likely to regain capacity and if so whether the decision can wait.

- Involve the person as fully as possible in the decision that is being made on their behalf.

- As far as possible, consider:

- the person's past and present wishes and feelings (in particular if they have been written down)
- any beliefs and values (e.g. religious, cultural or moral) that would be likely to influence the decision in question, and any other relevant factors, and
- The other factors that the person would be likely to consider if they were able to do so.

- As far as possible, consult other people if it is appropriate to do so and take into account their views as to what would be in the best interests of the person lacking capacity, especially:

- anyone previously named by the person lacking capacity as someone to be consulted

- anyone engaging in caring for or interested in the person's welfare

- any attorney appointed under a Lasting Power of Attorney

- any deputy appointed by the Court of Protection to make decisions for the person

- For decisions about serious medical treatment, where there is no one appropriate other than paid staff, healthcare professionals have to instruct an Independent Mental Capacity Advocate (IMCA)

- If the decision concerns the provision or withdrawal of life-sustaining treatment, the person making the best interests decision must not be motivated by a desire to bring about the person's death

- In the event that a best interest decision is made for a patient who lacks capacity to consent the following must be documented; the decision made, the rationale for the decision and the parties who were involved in the discussion. The decision maker is the individual who undertakes the provision of care.

7.1.9 The Mental Capacity Act Code of Practice makes it clear that the steps set out in the Act should form the starting point for considering all the relevant circumstances of each case, and often other factors will be important. Further guidance on interpreting best interests is provided in chapter 5 of the MCA 2005 Code of Practice (2007).

7.1.10 Healthcare professionals should demonstrate in their record-keeping that the decision has been based on all available evidence and has taken into account any conflicting views. What is in a person's best interests may well change over time. This means that even where similar actions need to be taken repeatedly in connection with the person's care or treatment, the person's best interests should be reviewed regularly.

7.1.11 In cases of serious doubt or dispute about an individual's mental capacity or best interests, an application can be made to the Court of Protection for a ruling. The duty officer of the Official Solicitor can advise on the appropriate procedure if necessary. See also chapter 8 of the Mental Capacity Act (2005) Code of Practice for further information. Details of the circumstances in which a referral should be made to the court are given in paragraph 26.

7.2 Duration of lack of capacity

7.2.1 The provisions of the Mental Capacity Act apply to acts or decisions made on behalf of an adult who lacks capacity – whether the lack of capacity is likely to be temporary or permanent. It is possible for capacity to fluctuate. In such cases, it is good practice to establish, while the person has capacity, their views about any clinical intervention that may be necessary during a period of anticipated incapacity, and to record these views. The person may wish to make an advance decision to refuse treatment (see section 6.14) or a statement of their preferences and wishes (see section 6.17). If the person does not make a relevant advance decision, decisions about that person's treatment if they lack capacity must be made in accordance with the Mental Capacity Act. This would include considering whether the person is likely to regain capacity and, if so, whether the decision can wait, as well as the statutory principle that all practical steps must be taken to enable the person to make their own decision.

7.3 Statements of preference and wishes

7.3.1 A healthcare professional must take all statements of a person's preferences and wishes into consideration as part of a best interests assessment. Written statements which request specific treatments made by a person before losing capacity should be given the same consideration as those made by people who currently have capacity to make treatment decisions.

7.3.2 However, a healthcare professional would not have to follow a written request if they thought that the specific treatment would be clinically unnecessary or not appropriate for the person's condition, and therefore not in the person's best interests. If the decision is different to a written statement, a healthcare professional should keep a record of this and be prepared to justify the decision if challenged.

7.3.3 There is an important legal distinction between a written statement expressing treatment preferences, which a healthcare professional must take into account when making a best interests decision, and a valid and applicable advance decision to refuse treatment, which healthcare professionals must follow. Healthcare professionals cannot ignore a written statement that is a valid and applicable advance decision to refuse treatment.

7.4 Lasting Power of Attorney (LPA)

7.4.1 The Mental Capacity Act enables a person aged 18 and over to appoint an attorney to look after their health and welfare decisions if they should lack the capacity to make such decisions in the future. Under a personal welfare LPA, the attorney – if they have the authority to do so – can make decisions that are as valid as those made by the person themselves. The LPA must be made in the form, and meet the criteria, set out in the regulations, and it must be registered with the Office of the Public Guardian before it can be used.

7.4.2 Please note there are two different types of Lasting Power of Attorney LPA); Property and Affairs who can only make decisions about financial matters, and Personal Welfare who can make decisions about both health and personal welfare.

7.4.3 The LPA may specify limits to the attorney's authority, and the LPA must specify whether or not the attorney has the authority to make decisions about life-sustaining treatment. Healthcare practitioners directly involved in the care or treatment of a person who lacks capacity should not agree to act as that person's attorney other than in exceptional circumstances (for example if they are the only close relative of the person). If the person lacks capacity and has created a personal welfare LPA, the attorney will have the authority to make decisions and consent to or refuse treatment as set out in the LPA. Healthcare practitioners should read the LPA if it is available, in order to understand the extent of the attorney's power.

7.4.4 The attorney must follow the statutory principles under the Mental Capacity Act and make decisions in the best interests of the person lacking capacity. If the decision is about life-sustaining treatment, the attorney must not be motivated by a desire to bring about the person's death. Attorneys also have a legal duty to have regard to the guidance in the Mental Capacity Act 2005 Code of Practice (2007). If there is a dispute that cannot be resolved, e.g. between the attorney and a doctor, it may have to be referred to the Court of Protection. More information about LPAs is given in chapter 7 of the MCA 2005 Code of Practice (2007)

7.5 Court appointed deputies

7.5.1 If a person lacks capacity to make a decision relating to their personal welfare, then the Court of Protection can make an order making a decision on their behalf. Alternatively, the Court of Protection can appoint a deputy to make decisions on behalf of the person who lacks capacity. The Mental Capacity Act makes it clear that in such situations it is preferable for the Court of Protection to make the decision if at all possible, and that if a deputy

is appointed, then their powers should be limited in scope to what is absolutely necessary.

7.5.2 The court must ensure that any deputy appointed has the necessary skills and abilities and is prepared to take on the duty and responsibility of the role. Both the court and any deputy must follow the statutory principles of the Act and make decisions in the person's best interests.

7.5.3 Deputies for personal welfare decisions will only be required in the most difficult cases, where important and necessary actions cannot be carried out without the court's authority or where there is no other way of settling the matter in the best interests of the person who lacks capacity. For example, a deputy could be appointed to make ongoing decisions, having consulted all relevant parties. This could be useful where there is a history of family disputes.

7.5.4 If a deputy has been appointed to make treatment decisions on behalf of a person who lacks capacity then it is the deputy rather than the healthcare professional that makes the treatment decision. A deputy cannot go against a decision of an attorney under an LPA made before the person lacks capacity. Deputies must follow the Mental Capacity Act's statutory principles and must make decisions in the person's best interests. A deputy cannot refuse consent to the provision of life-sustaining treatment.

More information about the powers of the Court of Protection and the role of deputies is given in chapter 8 of the MCA 2005 Code of Practice (2007)

7.6 Independent Mental Capacity Advocate (IMCA)

7.6.1 The Mental Capacity Act has, since April 2007 in England and since October 2007 in Wales, introduced a duty on NHS bodies to instruct an IMCA in serious medical treatment decisions when a person who lacks capacity to make a decision has no one who can speak for them, other than paid staff. In matters that meet the definition of serious medical treatment[4], IMCAs are only able to represent and support people whose treatment is arranged by the NHS. They have the right to information about an individual and can see relevant healthcare records.

7.6.2 The duties of an IMCA are to:

- Support the person who lacks capacity and represent their views and interests to the decision-maker
- Obtain and evaluate information, both through interviewing the person and through examining relevant records and documents
- Obtain the views of professionals providing treatment for the person who lacks capacity
- Identify alternative courses of action
- Obtain a further medical opinion, if required, and
- Prepare a report (that the decision-maker must consider).

7.6.3 IMCAs are not decision-makers for the person who lacks capacity. They are there to support and represent that person and to ensure that decision-making for people who lack capacity is done appropriately and in accordance with the Mental Capacity Act. More information is given at https://www.scie.org.uk/mca/imca/ and in chapter 10 of the Mental Capacity Act 2005 Code of Practice (2007)

In the event of a life threatening situation a best interest decision can be made to preserve life without the involvement of an IMCA but this decision will need to be clearly documented.

7.7 Consent forms

7.7.1 Where treatment is provided to a person who lacks capacity following a best interests decision, any consent form should not be signed by someone else unless they have a personal welfare LPA that authorises them to make the decision in question, or they are a court appointed deputy with similar authority. It is good practice to note either in the records or on a 'patient unable to consent' form why the treatment was decided to be in the patient's best interests.

7.8 Referral to court

7.8.1 The Mental Capacity Act established the Court of Protection to deal with decision-making for adults (and children in a few cases) who may lack the capacity to make specific decisions for themselves.

The Court of Protection deals with serious decisions affecting personal welfare matters, including healthcare, which were previously dealt with by the High Court. In cases of serious dispute, where there is no other way of finding a solution or when the authority of the court is needed in order to make a particular decision or take a particular action, the court can be asked to make a decision.

7.8.2 The courts have identified certain circumstances when referral should be made to them for a ruling on lawfulness before a procedure is undertaken. These are:

Decisions about the proposed withholding or withdrawal of artificial hydration and nutrition (ANH) from patients in a permanent vegetative state

- Cases involving organ, bone marrow or peripheral blood stem cell donation by an adult who lacks the capacity to consent (see chapter 3 for information on children)
- Cases involving the proposed non-therapeutic sterilisation of a person who lacks the capacity to consent to this (e.g. for contraceptive purposes), and
- All other cases where there is a doubt or dispute about whether a particular treatment will be in a person's best interests.

7.8.3 Other cases likely to be referred to the court include those involving ethical dilemmas in untested areas (such as innovative treatments for variant CJD[5]),

or where there are otherwise irresolvable conflicts between healthcare staff, or between staff and family members. More information about the powers of the Court of Protection and the cases that should be referred to the court is given in the Mental Capacity Act 2005 Code of Practice (2007) and in a Court of Protection Practice Direction.

7.8.4 The courts have stated that neither sterilisation which is incidental to the management of the detrimental effects of menstruation nor abortion need automatically be referred to court if there is no doubt that this is the most appropriate therapeutic response. However, these procedures can give rise to special concern about the best interests and rights of a person who lacks capacity. The need for such procedures occasionally arises in relation to women with a severe learning disability. It is good practice to involve as part of the decision-making process a consultant in the psychiatry of learning disability, the multidisciplinary team and the patient's family, and to document their involvement. Less invasive or reversible options should always be considered before permanent sterilization. Where there is disagreement as to the patient's best interests, a reference to the court may be appropriate.

7.8.5 Although some procedures may not require court approval, their appropriateness may give rise to concern. For example, some patients with learning disabilities may exhibit challenging behaviour. As with hysterectomies, great care must be taken in determining the best interests of such patients as distinct from dealing with the needs of carers and others who are concerned with the individual's treatment.

7.9 Research

7.9.1 The Mental Capacity Act sets out a legal framework for involving people who lack the capacity to consent to taking part in research. Anyone setting up or carrying out such research will need to make sure that the research complies with the provisions set out in the Act and will need to follow the guidance given in chapter 11 of the Mental Capacity Act 2005 Code of Practice (2007). The Act does not include clinical trials, which are covered by the Medicines for Human Use (Clinical Trial Regulations) 2004.

8.0 Children and Young People

The legal position concerning consent and refusal of treatment by those under the age of 18 is different from the position for adults. For the purposes of this policy 'children' refers to people aged below 16 and 'young people' refers to people aged 16 -17

8.1 Young people aged 16 – 17

8.1.1 By virtue of section 8 of the Family Law Reform Act 1969, people aged 16 or 17 are presumed to be capable of consenting to their own medical treatment, and any ancillary procedures involved in that treatment, such as an anaesthetic. As for adults, consent will be valid only if it is given voluntarily by an appropriately informed young person capable of consenting to the particular intervention. However, unlike adults, the refusal of a competent person aged 16–17 may in certain circumstances be overridden by either a person with parental responsibility or a court.

8.1.1 Section 8 of the Family Law Reform Act 1969 applies only to the young person's own treatment. It does not apply to an intervention that is not potentially of direct health benefit to the young person, such as blood donation or non-therapeutic research on the causes of a disorder. However, a young person may be able to consent to such an intervention under the standard of Gillick competence, considered below.

8.1.3 In order to establish whether a young person aged 16 or 17 has the requisite capacity to consent to the proposed intervention, the same criteria as for adults should be used. If a young person lacks capacity to consent because of an impairment of, or a disturbance in the functioning of, the mind or brain then the Mental Capacity Act 2005 will apply in the same way as it does to those who are 18 and over. If however they are unable to make the decision for some other reason, for example because they are overwhelmed by the implications of the decision, then the Act will not apply to them and the legality of any treatment should be assessed under common law principles. It may be unclear whether a young person lacks capacity within the meaning of the Act. In those circumstances, it would be prudent to seek a declaration from the court. More information on how the Act applies to young people is given in chapter 12 of the Mental Capacity Act 2005 Code of Practice (2007).

8.1.4 If the 16/17-year-old is capable of giving valid consent then it is not legally necessary to obtain consent from a person with parental responsibility for the young person in addition to the consent of the young person. It is, however, good practice to involve the young person's family in the decision-making process – unless the young person specifically wishes to exclude them – if the young person consents to their information being shared.

8.2 Children under 16 – the concept of Gillick competence

8.2.1 In the case of *Gillick*, the court held that children who have sufficient understanding and intelligence to enable them to understand fully what is involved in a proposed intervention will also have the capacity to consent to that intervention[6]. This is sometimes described as being 'Gillick competent'. A child under 16 may be Gillick competent to consent to medical treatment, research, donation or any other activity that requires their consent.

8.2.2 The concept of Gillick competence is said to reflect a child's increasing development to maturity. The understanding required for different interventions will vary considerably. Thus a child under 16 may have the capacity to consent to some interventions but not to others. The child's capacity to consent should be assessed carefully in relation to each decision that needs to be made.

8.2.3 In some cases, for example because of a mental disorder, a child's mental state may fluctuate significantly, so that on some occasions the child appears Gillick competent in respect of a particular decision and on other occasions does not. In cases such as these, careful consideration should be given as to whether the child is truly Gillick competent at the time that they need to take a relevant decision.

8.2.4 If the child is Gillick competent and is able to give voluntary consent after receiving appropriate information, that consent will be valid and additional consent by a person with parental responsibility will not be required. It is, however, good practice to involve the child's family in the decision-making process, if the child consents to their information being shared.

8.2.5 Where advice or treatment relates to contraception, or the child's sexual or reproductive health, the healthcare professional should try to persuade the child to inform his or her parent(s) or allow the medical professional to do so. If however the child cannot be persuaded, advice and/or treatment should still be given if the healthcare professional considers that the child is very likely to begin or continue to have sexual intercourse with or without advice or treatment and that unless they receive the advice or treatment then the child's physical or mental health is likely to suffer.

8.2.6 If the child seeks advice or treatment in relation to abortion and cannot be persuaded to inform her parent(s), every effort should be made to help the child find another adult (such as another family member or a specialist youth worker) to provide support to the child[7]

8.3 The requirement of voluntariness

8.3.1 Although a child or young person may have the capacity to give consent, this is only valid if it is given voluntarily. This requirement must be considered carefully. Children and young people may be subject to undue influence by their parent(s), other carers or a sexual partner (current or potential), and it is important to establish that the decision is that of the individual him or herself.

[7] *Axon v Secretary of State for Health* [2006] EWHC 37 (Admin)

8.4 Child or young person with capacity refusing treatment

8.4.1 Where a young person of 16 or 17 who could consent to treatment in accordance with section 8 of the Family Law Reform Act 1969, or a child under 16 but Gillick competent, refuses treatment, it is possible that such a refusal could be overruled[8] if it would in all probability lead to the death of the child/young person or to severe permanent injury.

8.4.2 The courts have, in the past, also found that parents can consent to their competent child being treated even where the child/young person is refusing treatment. However, there is no post-Human Rights Act 1998 authority for this proposition, and it would therefore be prudent to obtain a court declaration or decision if faced with a competent child or young person who is refusing to consent to treatment, to determine whether it is lawful to treat the child.

8.4.3 Where the treatment involved is for mental disorder, consideration should be given to using mental health legislation. The changes made to section 131 of the Mental Health Act 1983 by section 43 of the Mental Health Act 2007 mean that when a young person of 16 or 17 has capacity (as defined in the Mental Capacity Act 2005) and does not consent to admission for treatment for mental disorder (either because they are overwhelmed, do not want to consent or refuse to consent), they cannot then be admitted informally on the basis of the consent of a person with parental responsibility

8.4.4 A life-threatening emergency may arise when consultation with either a person with parental responsibility or the court is impossible, or the person with parental responsibility refuses consent despite such emergency treatment appearing to be in the best interests of the child. In such cases the courts have stated that doubt should be resolved in favour of the preservation of life, and it will be acceptable to undertake treatment to preserve life or prevent serious damage to health.

8.5 Child lacking capacity

8.5.1 Where a child under the age of 16 lacks capacity to consent (i.e. is not Gillick competent), consent can generally be given on their behalf by any one person with parental responsibility or by the court. As is the case where patients are giving consent for themselves, those giving consent on behalf of child patients must have the capacity to consent to the intervention in question, be acting voluntarily and be appropriately informed. The power to consent must be exercised according to the 'welfare principle': that the child's 'welfare' or 'best interests' must be paramount. Even where a child lacks capacity to consent on their own behalf, it is good practice to involve the child as much as possible in the decision-making process.

8.5.2 Where necessary, the courts can overrule a refusal by a person with parental responsibility. It is recommended that certain important decisions, such as sterilisation for contraceptive purposes, should be referred to the courts for guidance, even if those with parental responsibility consent to the operation going ahead.

8.5.3 The European Court of Human Rights judgment in a case where doctors treated a child contrary to his mother's wishes, without a court order[9], made clear that the failure to refer such cases to the court is not only a breach of professional guidance but also potentially a breach of the European Convention on Human Rights. In situations where there is continuing disagreement or conflict between those with parental responsibility or those with

[8] *Re W (a minor) (medical treatment)* 1992] 4 All ER 627
[9] *Glass v The United Kingdom* -61827-00 [2004] ECHR 103

parental responsibility and the doctors, and where the child is not competent to provide consent, the court should be involved to clarify whether a proposed treatment, or withholding of treatment, is in the child's best interests. Parental refusal can only be overridden in an emergency.

8.5.4 A child can only have two legal parents but there is no limit to the number of people who can share parental responsibility. The Children Act 1989 sets out persons who may have parental responsibility. These include (this list is not exhaustive):

- The child's birth mother automatically has parental responsibility
- The child's father, if he was married to the mother at the time of birth and who is named on the birth certificate. This will not be lost if the parents later divorce.
- Unmarried father whos name is in the certificate for a birth registered after 1st December 2003.
- Unmarried fathers, who can acquire parental responsibility

- Non-birth mothers, who are not considered legal parents but who are married or in a civil partnership with the birth mother, can acquire parental responsibility by signing an agreement with the birth mother.

- For same sex male relationships, an order can be gained which is issued by the Court to the intended parents of a surrogate child and extinguishes the legal parenthood of the surrogate mother and, if she has one, her partner. The order reassigns legal parenthood and parental responsibility to the intended parents.

- Any family member in receipt of a Special Guardianship Order will have parental responsibility for the duration stated on the order e.g. grandparents.

- An adoptive parent will acquire parental responsibility on adoption
- The child's legally appointed guardian
- A person in whose favour the court has made a residence order concerning the child
- A local authority designated in a care order in respect of the child
- A local authority or other designated person who holds an emergency protection order in respect of the child

Who does not automatically have it?

Unmarried fathers do not automatically have parental responsibility. They can gain this by:

- Marrying the mother.
- Having his name registered or re-registered on the birth certificate. (An unmarried father on a birth certificate before 1st December 2003 will not have parental responsibility and will need to re-register.)
- Making a parental responsibility agreement with the mother.
- Obtaining a parental responsibility order from the Court.
- Obtaining a residence order from the Court.
- Becoming the child's guardian on the mother's death.

Step parents can apply for parental responsibility through a legally bound agreement

Looked After Child (LAC)

If the child is subject to a care order and placed in foster care, responsibility is shared between the parents and Local Authority. Consent must be given by a senior manager within Social Services and the child's social worker should be instrumental in obtaining this.

Please ensure that an appropriate person with parental responsibility accompanies the child/young person to their treatment.

A useful guide to parent responsibility can be found at: http://www.childrenslegalcentre.com and www.stonewall.org.uk

8.5.5 Where there is doubt about whether a parent is acting in the interests of the child or young person, then the healthcare practitioner would be unwise to rely on the parent's consent, for example if a child alleges abuse and the parent supports psychiatric treatment for the child. The Government's guidance *Working Together to Safeguard Children* covers situations involving parental consent where abuse or neglect is suspected.

8.5.6 In order to consent on behalf of a child, the person with parental responsibility must themselves have capacity. Where the person with parental responsibility for a child is themselves under 18, they will only be able to give valid consent for the child's treatment if they themselves are Gillick competent. Whether or not they have capacity may vary, depending on the seriousness of the decision to be taken.

8.5.7 Where a child is a ward of court, no important step may be taken without the prior consent of the court. This is likely to include more significant medical interventions but not treatment for minor injuries or common diseases of childhood

8.5.8 In an emergency it is justifiable to treat a child who lacks capacity without the consent of a person with parental responsibility, if it is impossible to obtain consent in time and if the treatment is vital to the survival or health of the child

8.5.9 If the child is subject to a care order and placed in foster care, staff should be aware that responsibility is shared between the parents and Local Authority.

8.5.10 If parents do not have parental responsibility, then they cannot be involved in the decisions about the health care of the child.

9.0 Refusal of Treatment

If the process of seeking consent is to be a meaningful one, refusal must be one of the patient's options. A competent adult patient is entitled to refuse any treatment, except in circumstances governed by the Mental Health Act.

Under the Mental Capacity Act 2005, If an adult patient lacks capacity, they may have refused treatment in an **Advance Decision**; the terms of which should then be honoured, if it is valid and applicable to the circumstances. A designated decision-maker, acting on behalf of an adult patient who lacks capacity, also has the right to refuse treatment on behalf of the patient; though the right to refuse life-saving treatment will depend on express authorisation to do so having been given under the terms of the Personal & Welfare Lasting Power of Attorney.

The situation for children is more complex: see the Department of Health's Seeking consent: working with children for more detail (link). Essentially, whilst in law the refusal of a child under 16 to consent may be overridden by the consent of a person with parental responsibility, health professionals are encouraged always to try to obtain a competent child's consent before providing treatment, unless any delay involved in so doing would put the child's life or health at risk. It is recognised that decision-making with older children will often be a matter of negotiation between the child, those with parental responsibility and clinicians. Efforts should be made to ensure that children don't feel that decisions are being made over their heads. 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 while still having capacity, 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.

In the case of patients who are Jehovah's Witnesses, the refusal to accept blood or blood products should be noted on the consent form, under the statement by the patient relating to "Procedures which I do not wish to be carried out".

An advance decision made by a capable patient must be respected by the healthcare professional and treatment should be provided in accordance with the same.

This healthcare professional must consult with any Legal Power of Attorney that has been lawfully appointed to make decisions on behalf of a patient in the event that they lose capacity.

10.0 Statement of evidence/references

Reference guide to consent for examination or treatment provides a comprehensive summary of the current law on consent and includes requirements of regulatory bodies such as the General Medical Council where these are more stringent. Copies may be accessed on the internet at https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/138296/dh_103653__1_.pdf

Specific guidance, incorporating both the law and good practice advice, is available for health professionals working with children, with people with learning disabilities and with older people. Copies of these booklets are available on the Internet at. https://www.gov.uk/government/organisations/department-of-health

General Medical Council (GMC) (2008) Consent: patients and doctors making decisions together.

Department of Health (DH) Reference guide to consent for examination or treatment second edition). DH July 2009 https://www.gov.uk/government/publications/reference-guide-to-consent-for-examination-or-treatment-second-edition

Mental Capacity Act 2005 http://www.legislation.gov.uk/ukpga/2005/9/contents

Mental Capacity Act 2005 Code of Practice (2007) http://www.justice.gov.uk/downloads/protecting-the-vulnerable/mca/mca-code-practice-0509.pdf

Montgomery Supreme Court Ruling https://www.supremecourt.uk/decided-cases/docs/UKSC_2013_0136_Judgment.pdf

Children's Legal Centre; 'Parental Responsibility' July 2006. Aneurin Bevan Health Board: 'Parental responsibility' Children's Occupational Therapy. June 2010.

11.0 Governance

11.1 Document review history

Version number	Review date	Reviewed by	Changes made
1	09/2002	Medical Director	New Policy
2	11/2004	Medical Director	Review and update
3	09/2006		Review and update
4	03/2008		Appendix K replaced
5	05/2008		Appendix K updated as a link
6	09/2008		Document updated to reflect legislative changes
7	09/2011		Document updated to reflect legislative and regulatory changes
8	04/2012		Minor change to inquest diagram
9	11/13		Review & update post 2012 never event & to map NHSLA standards
10	18/8/15		Legislative changes post policy review by Trust's legal providers
11	16/12/19		Policy review

11.2 Consultation History

Stakeholders Name/Board	Area of Expertise	Date Sent	Date Received	Comments	Changes Made
Capsticks Legal Team	Law	7 July 2015		Yes	Policy redrafted to meet changes post Montgomery legal ruling
Clinical Board	Cross specialty	9 September 2015	Sep – December 2015	Yes: Postal votes Straight to test Anaesthetic consent Consent stickers Nurse consenting Interventional procedure consenting Documenting withdrawn consent Consenting in OPD setting – capacity	(Discussed after Montgomery presentation in January 2016 by Capsticks with some changes made)
Acute User – Consultant, Matrons & Heads of Departments	Cross specialty	September 2015	Sep – October 2015	As above	As above
Consultant, Matrons & Heads of Departments	Cross specialty	August 2019	August 2019	Paedatric information received, Head of Midwifery review, various consultant responses	Additonal information to support paediatric consent. Addition of consent to robotic surery

11.3 Audit and monitoring

This Policy outlines the process for document development will be monitored on an ongoing basis. The centralisation of the process for development of documents will enable the Trust to audit more effectively. The centralisation in recording documents onto a Quality Management database will ensure the process is robust.

Audit/Monitoring Criteria	Tool	Audit Lead	Frequency of Audit	Responsible Committee/Board
Monitoring of incidents reported where consent has been compromised	Documentation Audit	Speciality audit lead	Annually	CAEB
Process of obtaining and recording consent				

11.4 Equality Impact Assessment

As part of its development, this policy and its impact on equality has been reviewed. The purpose of the assessment is to minimise and if possible remove any disproportionate impact on the grounds of race, gender, disability, age, sexual orientation, religion or belief, pregnancy and maternity, gender reassignment or marriage and civil partnership. No detriment was identified.

Equality Impact Assessment			
Division		**Department**	
Person completing the EqIA		**Contact No.**	
Others involved:		**Date of assessment:**	
Existing policy/service		**New policy/service**	

Will patients, carers, the public or staff be affected by the policy/service?	Staff
If staff, how many/which groups will be effected?	All staff

Protected characteristic	**Any impact?**	**Comments**
Age	NO	Positive impact as the policy aims to recognise diversity, promote inclusion and fair treatment for patients and staff
Disability	NO	
Gender reassignment	NO	
Marriage and civil partnership	NO	
Pregnancy and maternity	NO	
Race	NO	
Religion or belief	NO	
Sex	NO	
Sexual orientation	NO	

What consultation method(s) have you carried out?	*For example: focus groups, face-to-face meetings, PRG, etc*
How are the changes/amendments to the policies/services communicated?	*For example: email, meetings, intranet post, etc*

What future actions need to be taken to overcome any barriers or discrimination?

Who will lead this?	Who will lead this?	Who will lead this?	Who will lead this?
Review date of EqIA			

Appendix 1: Consent Quick Reference Guide

13 key points on consent: the law in England
When do health professionals need consent from patients?

1. Before you examine, treat or care for competent adult patients you must obtain their consent.

2. Adults are always assumed to be competent unless demonstrated otherwise. If you have doubts about their competence, the question to ask is: "can this patient understand and weigh up the information needed to make this decision?" Unexpected decisions do not prove the patient is incompetent but may indicate a need for further information or explanation.

3. Patients may be competent to make some health care decisions, even if they are not competent to make others.

4. Giving and obtaining consent is usually a process, not a one-off event. Patients can change their minds and withdraw consent at any time. If there is any doubt, you should always check that the patient still consents to your caring for or treating them.

Can children give consent for themselves?

5. Before examining, treating or caring for a child, you must also seek consent. Young people aged 16 and 17 are presumed to have the competence to give consent for themselves. Younger children who understand fully what is involved in the proposed procedure can also give consent (although their parents will ideally be involved). In other cases, some-one with parental responsibility must give consent on the child's behalf, unless they cannot be reached in an emergency. If a competent child consents to treatment, a parent **cannot** over-ride that consent. Legally, a parent can consent if a competent child refuses, but it is likely that taking such a serious step will be rare.

Who is the right person to seek consent?

6. It is always best for the person actually treating the patient to seek the patient's consent. However, you may seek consent on behalf of colleagues if you are capable of performing the procedure in question, or if you have been specially trained to seek consent for that procedure.

What information should be provided?

7. Patients need sufficient information before they can decide whether to give their consent: for example information about the benefits and risks of the proposed treatment, and alternative treatments. If the patient is not offered as much information as they reasonably need to make their decision, and in a form they can understand, their consent may not be valid.

8. Consent must be given voluntarily: not under any form of duress or undue influence from health professionals, family or friends.

Does it matter how the patient gives consent?

9. No: consent can be written, oral or non-verbal. A signature on a consent form does not itself prove the consent is valid – the point of the form is to record the patient's decision, and also increasingly the discussions that have taken place. Your Trust or organisation may have a policy setting out when you need to obtain written consent.

Refusal of treatment

10. Competent adult patients are entitled to refuse treatment, even when it would clearly benefit their health. The only exception to this rule is where the treatment is for a mental disorder and the patient is detained under the Mental Health Act 1983.

11 A competent pregnant woman may refuse any treatment, even if this would be detrimental to the fetus.

Adults who do not have the capacity to give consent

12. **No-one** can give consent on behalf of an adult without the capacity to consent (except under some circumstances when the person has appointed a Lasting Power of Attorney to make specific health decisions or has been appointed to do so by the Courts). However, you may still treat such a patient if the treatment would be in their best interests. 'Best interests' go wider than best medical interests, to include factors such as the wishes and beliefs of the patient when competent, their current wishes, their general well-being and their spiritual and religious welfare. People close to the patient may be able to give you information on some of these factors. Where the patient has never been competent, relatives, carers and friends may be best placed to advise on the patient's needs and preferences.

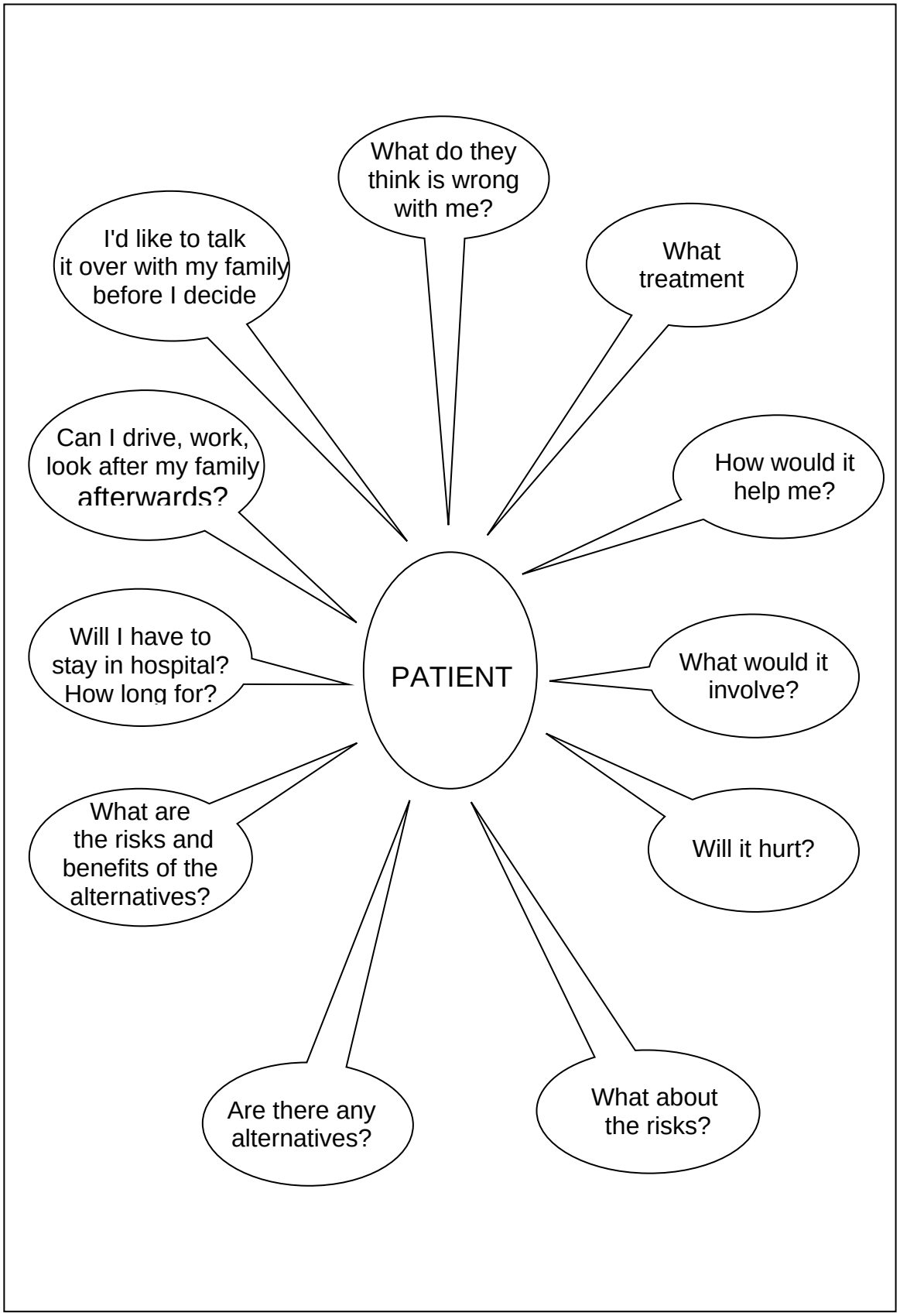
13. If a person who lacks capacity has clearly indicated in the past, while competent, that they would refuse treatment in certain circumstances (an 'advance refusal'), and those circumstances arise, you must abide by that refusal.

This summary cannot cover all situations. For more detail, consult the *Reference guide to consent for examination or treatment,* available from the NHS Response Line 08701 555 455 at https://www.gov.uk/government/publications/reference-guide-to-consent-for-examination-or-treatment-second-edition

Appendix 2: Current list of consent forms in use in Milton Keynes Hospital NHS Foundation Trust

Consent Form 1	Patient agreement to investigation or treatment
Consent Form 2	Parental agreement to investigation or treatment for a child or young person
Consent Form 3	Patient/Parental agreement to investigation or treatment (Procedures where consciousness not impaired)
Consent Form 4	Form for adults who are unable to consent to investigation or treatment
Consent Form	Urological Surgery – Agreement to Investigation or Treatment (Form1)
Consent Form	Ophthalmic procedures-Agreement to investigation or treatment
Consent to Post Mortem	Consent to a hospital post mortem examination on a baby or child Consent to a hospital post mortem examination on an adult

Appendix 3: Seeking consent: remembering the patient's perspective



Appendix 4: The Human Rights Act 1998

The Human Rights Act 1998

The Trust aims to ensure that all policies and procedures are compliant with the Human Rights Act 1998 which came into force in October 2000 and incorporates into English law the European Convention on Human Rights. Where it is not clear whether any particular action may contravene the Act, or where there appears to be a conflict between competing human rights, legal advice should be sought and documented. In the first instance the Legal Manager or the Medical Director should be consulted and an expert legal opinion obtained if necessary

The extracts from the European Convention that should be considered alongside this policy are:

- Article2: Right to life
- Article 3: Right to freedom from inhuman and degrading treatment (could cover medical research)
- Article 8: Right to respect for private and family life
- Article 9: Freedom of thought, conscience and religion (especially in the case of Jehovah's Witnesses

Because of the implications of the Act, the Trust should seek legal advice whenever capacity is uncertain or whenever a patient lacks capacity but the close relatives disagree with the proposed treatment.

Appendix 5: Consent and the Responsibility of Health Professionals

Consent may be obtained by a medical practitioner, dentist or other health care professional. However, it is **not** appropriate to delegate the obtaining of consent to a junior doctor or other health care professional with insufficient understanding of the proposed procedure. Medical practitioners and all health care professionals are responsible for ensuring that, **before the start of any examination or treatment,** the patient has been given sufficient time and information to make an informed decision and has given consent to the procedure or investigation.

In respect of medical practitioners, the GMC in 'Seeking Patients' Consent: the Ethical Considerations' 1999 offers the following guidance;

'If you are the doctor providing treatment or undertaking an investigation, it is your responsibility to discuss with the patient and obtain consent, as you will have a comprehensive understanding of the procedure or treatment, how it is carried out, and the risks attached to it. Where this is not practicable, you may delegate these tasks provided you ensure that the person to whom you delegate:

- ***is suitably trained and qualified;***
- ***has sufficient knowledge of the proposed investigation or treatment, and understands the risks involved and if possible*** **be competent** to perform the treatment or procedure in question.
- ***acts in accordance with the guidance in this [GMC]booklet'*** (as referred to above, page 9).
- No Pre registration doctors (FY1'S) are allowed to obtain consent.
- All Registered doctors (FY2'S) and above are either trained to perform procedures or trained to take consent for the procedure.
- Any healthcare practitioners taking consent are expected to keep a record in their log books plus additional documentation of procedures they are trained to perform and/or obtain consent.
- Consultants teach and supervise the consenting process for all other junior medical staff and authorise them to obtain consent or perform a particular procedure.
- All medical practitioners must ensure that rules are followed in the process of consenting patients for examination and treatment.
- If a healthcare practitioner taking consent is unable to answer all questions raised by the patient, the practitioner is to seek advice from a more senior practitioner and respond appropriately to the patient.

For health care professionals **other than medical practitioners** who undertake to obtain consent, for example:

- in nurse-led clinics
- nurse practitioners
- urology clinical practitioners
- nurse endoscopists
- midwives
- professions allied to medicine

the GMC principles will also apply provided that the following criteria are complied with.

The health care professional obtaining the consent:

- **must** have **achieved and maintained** the agreed competencies in obtaining informed consent
- **must** be fully conversant with the procedure for which consent is being sought.

The patient undergoing the treatment or procedure:

- **must be** made aware of the implications of the treatment including pre-operative, peri-operative, and post-operative effects and consequences
- **must wherever possible be provided with** adequate literature describing the procedure, its benefits, risks and alternatives and the opportunity offered to discuss this information with the health care professional concerned.
- **must** be aware of the professional background of the health care professional concerned and also have access to the delegating health care professional, if required, to answer any outstanding questions**.**

Appendix 6: Advance Directives (or Living Wills)

Some patients who lack capacity may have an 'Advance Directive'. 'Advance Directives' (sometimes termed living wills), are statements made by patients, when competent, about how they wish to be treated should they become incompetent at some stage in the future. The statement will have legal force provided the patient:

- is competent when making the advance statement;
- has sufficient information to make an informed choice;
- makes that choice voluntarily.

and

- the advance directive is sufficiently specific to be applicable to the treatment in question;
- there is no reason to believe that the patient has changed his/her mind.

Failure to abide by a valid advance directive leaves a doctor vulnerable to civil or criminal proceedings in battery and disciplinary proceedings before the General Medical Council.

Health professionals must, therefore, respect any refusal of treatment stipulated when the patient was competent, provided the above criteria are met. For further information please see 'Guidelines for Dealing With Patients who Have an Advance Directive/Living Will' the British Medical Association's 1995 guidance "Advance Statements about Medical Treatment" and "Reference Guide to Consent for Examination or Treatment (2001) Section 19 to 19.3, Chapter 1.

Appendix 7: CORONERS REFERRAL – leading possibly to Post Mortem and/or inquest