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Informed Consent Policy

Document Classification

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Preview/Introduction

This policy aims to ensure best practice in consent.

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

Consent must be obtained before any examination or treatment. It may be non-verbal (e.g., offering a wrist for taking a pulse), oral or written. Not all consent needs to be written, but written consent can provide evidence that consent has been discussed with the patient.
Consent is a continuous process rather than a one-off decision. It is important that patients are given continuing opportunities to ask further questions and to review decisions about their health care. In recent case law *[Montgomery v Lanarkshire Health Board, 11 March 2015],* the Supreme Court has firmly stated that informed consent is now part of English law. Montgomery confirms that the duty on the part of healthcare professionals is to ensure that a patient is aware of the material risks involved in the treatment and of any reasonable alternative or variant to that treatment. This duty is not discharged by 'simply providing technical information or by the routine signature on a consent form' - the expectation is that there should be an appropriate dialogue during which information should be shared in a way that is comprehensible to the patient. In recognition of the significance of consent to care and treatment, the Care Quality Commission (CQC) includes 'need for consent' as one of its fundamental standards which came into force on 1 April 2015. Breaches of 'need for consent' or its components will constitute a prosecutable offence. This means that where care and treatment is given without valid consent, and/or against the specific wishes of the patient or without lawful authority, the CQC can move directly to prosecution without first serving a warning notice. The Department of Health and General Medical Council have both issued guidance documents on consent to care and treatment. These should be consulted for details of the law and good practice standards on consent to examination and treatment:

- www.dh.gov.uk/consent ; and
- www.gmc-uk.org

Scope

This policy applies to all of our staff working across the Totally Group regardless of who the lead contractors are. The policy applies to all staff who have direct contact with people providing our urgent and elective care and treatment. It also includes many departments who may not work directly with patients, families, and carers, but whose activities affect the quality of care and service we provide, for example business development.

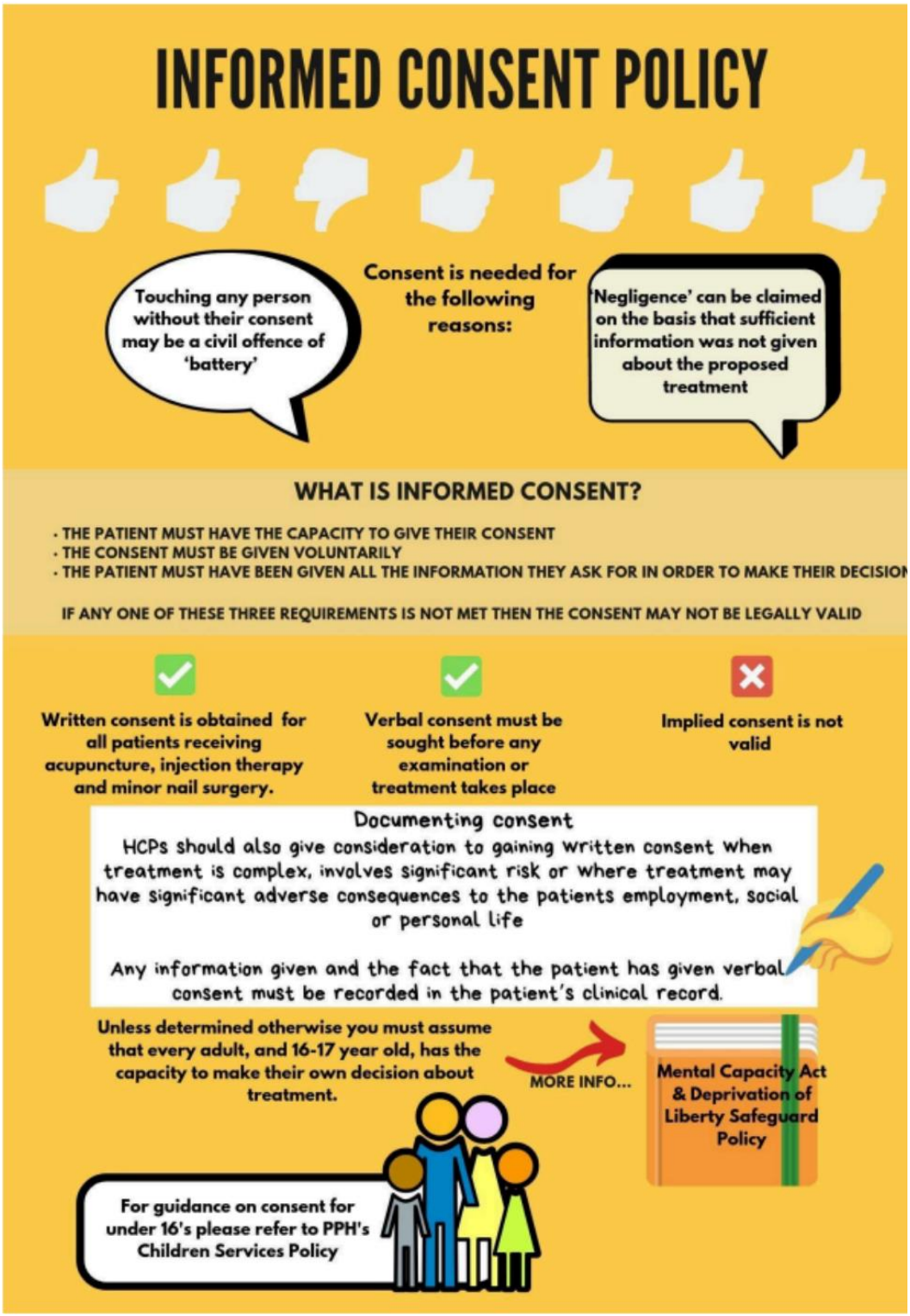
Consultation

Medical Director
Director of Nursing and Quality
Governance Leads
Policy Lead

Related Policies

Totally Safeguarding Children and Adults at Risk of Harm or Abuse Policy

Quick Reference Guide (if applicable)



Please note: All staff should ensure that they understand this section fully and follow any instructions in order to minimise patient, staff and organisational risks. This is not a replacement for ensuring that you understand the details of this policy. It simply acts to remind you of the essential steps that must be taken to fulfil the needs of the organisation.

Responsibilities

The Chief Operating Officer has accountability for the safe treatment and care of Totally patients by its staff and contractors (statutory duty of quality and clinical governance).

Medical Director is responsible for ensuring there is an up-to-date consent policy and that compliance with the law and professional conduct surrounding consent is maintained.

Directors/Heads of Services are responsible for:

- ensuring that the requirements of this policy are included in local induction and training;
- ensuring that all healthcare professionals in their division/specialty understand the principles of consent outlined in this policy;
- ensuring that staff to whom consent is delegated (i.e., staff who are not capable of performing the procedure, but are trained to take consent in it) have undergone the requisite training and competency assessment;

All Employees/Healthcare professionals must ensure that the patient is genuinely consenting to what is being proposed. The healthcare professional carrying out the examination or treatment is ultimately responsible for ensuring valid consent has been obtained; it is they who will be held responsible in law if this is challenged later.

Implementation, Distribution and Training

Implementation and Distribution

All Totally policies are controlled, stored, disseminated and accessed on the My Totally Intranet via the knowledge and policies links.

Training

Mandatory training for consultants, SpRs, and specialist nurses undertaking or taking consent for procedures.

The Level 2 Safeguarding Vulnerable Adults training programme includes training in the principles of consent and the specific consent requirements of the Mental Capacity Act 2005. It is mandatory for this training to be undertaken annually by all clinical staff

Records of training and evidence of competency assessments must be maintained to allow Totally to identify clinical staff who are not capable of performing the procedure but who are authorised to obtain consent for that procedure.

Aims and Objectives

1. Healthcare professionals must obtain valid consent before examination or treatment.
2. Valid consent means obtaining consent from a properly informed person who has the capacity to consent, free from undue influence.
3. Assessment of capacity is a two-stage test involving the patient's ability to make a particular decision at a particular time. Where a patient's capacity is in doubt, assessment should be made in writing in the medical or nursing notes.
4. For adults who lack capacity, staff should consult the Mental Capacity Act Policy, and have regard to the Mental Capacity Act Code of Practice. Staff should also be aware that the patient may have an attorney (person with a lasting power of attorney for health and welfare decisions – LPA), an independent mental capacity advocate (IMCA) or a court appointed deputy acting on their behalf.
5. A patient is free and able to change their mind or withdraw their consent at any time. Patients may change their mind over time; it is for the healthcare professional to ensure that consent is still valid at the time of the intended procedure.
6. A patient is entitled to refuse consent and may also have made an advance decision to refuse treatment (ADRT).
7. The person performing the examination or treatment is responsible for ensuring that valid consent has been given. In some specialties, other staff may seek consent provided they have been trained and assessed as competent to do so. This is known as delegated consent.
8. Young people aged 16-17 are presumed to be able to consent for themselves subject to their having capacity to make the decision in question [s8 Family Law Reform Act 1969 and Mental Capacity Act 2005]. Children below 16 may be competent to give consent depending on their maturity and the nature of the decision [see paras 6.2.5, 6.2.6 and Appendix 1]. Any conversations with children must be pitched at an appropriate level for their level of understanding.
9. Where a child is not competent to give consent, only a person (or body) with parental responsibility may consent on the child's behalf [see Appendix 1].
10. Consent may be non-verbal (eg. offering a wrist for taking a pulse), oral or written. Not all consent needs to be written, but written consent can provide evidence that consent has been discussed with the patient.
11. There are four generic consent forms for use by healthcare professionals:
    - Form 1 - Patient agreement to investigation or treatment
    - Form 2 - Parent or person (who has parental responsibility) agreement to investigation or treatment for a child or young person
    - Form 3 - Patient/parental agreement to investigation or treatment for procedures where consciousness is not impaired
    - Form 4 - Form for adults who are unable to consent to investigation or treatment

Only fully signed consent forms should be stored in a patient's health record.

Definitions

Advance decision to refuse treatment (ADRT) - Means a decision made by a patient to refuse a specific treatment made in advance by a person who has capacity to do so. This decision will then apply at a future time when that person lacks capacity to consent to, or refuse, the specified treatment (previously known as a living will or advance directive)

Specific rules apply to advance decisions to refuse life - sustaining treatment.

A person who lacks capacity - Means (as defined in the Mental Capacity Act 2005) a person who is unable to make decisions for themselves because of an impairment or disturbance in the functioning of their mind or brain whether permanent or temporary.

Consent - A patient's agreement for a healthcare professional to provide care. For consent to be valid the patient must:

- Be competent to make the particular decision
- Understand information relevant to the decision and be able to retain that information and use and weigh that information in the balance as part of the process of making the decision
- Have received sufficient information to make the decision
- Not be acting under duress
- Be able to communicate their decision

Child - Means for the purposes of this policy anyone under 16 years of age

Court appointed deputy - Means a person appointed by the Court of Protection to make decisions on behalf of a person who lacks capacity

Independent Mental Capacity Advocate (IMCA) - Means a person appointed to support the person who lacks capacity and represent their views but who is not empowered to make decisions.

Lasting Power of Attorney (LPA) - Means a legal document, registered with the Office of the Public Guardian, appointing an attorney to act on the patient's behalf according to the terms of the document.

Parental responsibility - Means all the rights, duties, powers, responsibilities and authority which by law a parent has in relation to the child and his/her property. For more information about persons with parental responsibility see Appendix 1.

Responsible healthcare professional - Means the clinician providing the treatment, investigation or examination. If this is not the consultant, the consultant responsible for the person's care, will remain ultimately responsible for the quality of medical care provided.

Young person - Means for the purposes of this policy a person aged 16 to 17 years of age (inclusive).

Process

1. Valid consent

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

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

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

In some cases, the healthcare 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 healthcare professional will help the patient to decide between them.

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

The validity of consent does not depend on the form in which it is given. Written consent merely serves as evidence of consent; if the elements of voluntariness, appropriate information and capacity have not been satisfied, a signature on a form will not make consent valid.

What does 'voluntarily' mean?

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

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

Totally staff should be aware of Totally’s policy on safeguarding vulnerable adults, which aims to protect people against abuse. The term 'abuse' has a very wide definition and includes acts of omission and neglect as well as other forms of abuse.

2. Who can give consent?

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

- they are the patient; or
- someone with parental responsibility for the patient; or
- someone authorised to act on the patient's behalf such as a person appointed under a lasting power of attorney for health and welfare decisions (LPA) or a court appointed deputy

a) Adult patients with capacity

Adults are always assumed to be competent to give consent unless demonstrated otherwise. A patient who is judged competent to consent to a procedure must have:

- the mental capacity to understand the nature of the procedure to which he/she is consenting; and
- be in possession of all the material facts regarding the nature of the procedure the material risks involved, including the comparative risks of different treatment options; and
- ongoing management after the procedure.

They must also be able to communicate their decision to the treating team in some way – by speech, writing, signalling, or some other means (e.g. eye-pointing).

b) Adults without capacity

Where any doubt exists about a patient's mental capacity, appropriate professionals should assess the capacity of the person using the two-stage capacity test.

No adult can consent on behalf of another adult unless:

a) They have been authorised to act on the patient's behalf (i.e. appointed under a Lasting Power of Attorney which specifically includes health and welfare decisions; or are a Court Appointed Deputy); or

b) They are a responsible healthcare professional, in which case a patient's lack of capacity must have been established and documented by completion of the two-stage test of capacity; the proposed care and treatment is justifiably in the patient's best interests and this is described, and has not been refused in advance in a valid and applicable advance decision to refuse treatment (ADRT).

For further details about advance decisions to refuse treatment see the Department of Health's Reference Guide to consent for examination or treatment) and the Mental Capacity Act Code of Practice (chapter 9).

c) Adults with learning disabilities

Adults with learning disabilities are presumed to be capable of taking health care decisions, including giving or refusing consent, unless the opposite has been demonstrated. Where any doubt exists, appropriate professionals should assess the capacity of the person using the two-stage capacity test and best interest checklist.

The health care professional should involve appropriate colleagues such as specialist learning disability liaison team members and speech and language therapists in making assessments of capacity where communication difficulties are suspected, unless the urgency of the patient's situation prevents this. If at all possible, the patient should be assisted to make and communicate their own decision, for example by providing information in non-verbal ways.

For further information on this, please see chapter 3 of the Mental Capacity Act Code of Practice.

d) Patients who have self-harmed

Cases of self-harm present a particular difficulty for healthcare professionals. Where the person is able to communicate, an assessment of their mental capacity should be made as a matter of urgency using the two-stage capacity test. If the person is assessed as not having capacity, then they may be treated in their best interests.

Patients who have attempted suicide and are unconscious should be treated if any doubt exists as to either their intentions or their capacity when they took the decision to attempt suicide.

If a patient with capacity has harmed themselves, a prompt psychosocial assessment of their needs should be offered. However, if the person refuses treatment and use of the

Mental Health Act is not appropriate, then their refusal must be respected.2 Similarly, if practitioners have good reason to believe that a patient genuinely intended to end their life and had capacity when they took that decision, and are satisfied that the Mental Health Act is not applicable, then treatment should not be forced upon the person although clearly attempts should be made to encourage the patient to accept help.

e) Young people [over 16 and under 18] – please also refer to Appendix 1

As soon as a child reaches the age of 16, he/she has the right to be treated as an adult and can give effective consent to treatment, both for surgical treatment and any ancillary procedure such as the administration of anaesthetic. This is subject to their having capacity to make the decision in question as per the Mental Capacity Act 2015. However, until their 18th birthday a parent can still consent on his/her behalf. The refusal of a competent person aged 16 or 17 may therefore, in certain circumstances, be overridden by a person with parental responsibility (see Appendix 1) or by the court. This power to overrule must be exercised on the basis that the mental and physical welfare of the young person is considered first and foremost in the decision-making process.

f) Children [under 16] - please also refer to Appendix 1

Any young person regardless of age can independently seek medical advice and give valid consent to treatment, if, in the opinion of the healthcare professional, they are capable of understanding the nature and possible consequences of the procedure and are mature enough to make the decision [Gillick v West Norfolk & Wisbech Area Health Authority3].

The concept of Gillick competence is considered to reflect a child's increasing development to maturity.

This principle also applies to decisions about treatment and care for sexually transmitted infections, contraception and termination [R (Axon) v Secretary of State for Health]. In particular, children and young people should understand the potential risks and longer-term effects of termination (see Appendix 1).

As the understanding required for different interventions will vary considerably, a child under 16 may therefore have the capacity to consent to some interventions but not

others. Where a child under 16 but Gillick competent refuses treatment, such a refusal can be overruled by a person with parental responsibility or by the court. This power to overrule must be exercised on the basis that the mental and physical welfare of the child is considered first and foremost in the decision-making process.

A life-threatening emergency may arise in situations where consultation with either the

person with parental responsibly or court is impossible, or the person with parental responsibility refuses consent despite such emergency treatment appearing to be in the best interest of the child. In such cases the courts have stated that doubt should be resolved in favour of preservation of life and it will be acceptable to undertake treatment to preserve life or prevent serious damage to health.

g) Children with learning disabilities

As with adults, a child with a learning disability should not be assumed to be incapable of taking health care decisions, including giving or refusing consent, unless the opposite has been demonstrated. Where any doubt exists, appropriate professionals should assess the capacity of the child.

h) Treatment of children and parental consent (see Appendix 1 for definitions of those with parental responsibility)

When babies or young children are being cared for in hospital, it will not usually be practicable to seek their parents' consent on every occasion for every routine intervention such as blood or urine tests or X-rays. However, in law, such consent is required. Where a child is admitted to hospital, healthcare professionals should discuss with their parent(s) what routine procedures will be necessary, and ensure that their consent for these interventions is agreed in advance. If parents specify that they wish to

be asked before particular procedures are initiated, the healthcare professional must do so, unless the delay involved in contacting them would put the child's health at risk.

Only people with 'parental responsibility' are entitled to give consent on behalf of their children. Healthcare professionals must be aware that not all parents have parental responsibility for their children (for example, unmarried fathers do not automatically have such responsibility although they can acquire it). If a healthcare professional is in any doubt about whether a person with the child has parental responsibility for that child, they must check.

i) Specific contentious circumstances

Specific issues may arise in relation to cases involving mental incapacity, sterilisation or refusal of blood products for religious reasons (eg. Jehovah's witnesses). Where doubt exists regarding who may give consent, a cautious approach should be adopted (with the exception of life-threatening / emergency situations) and further advice should be sought from a member of the governance team before proceeding.

3. Who should seek consent?

a) General principles

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

Where oral or non-verbal consent is being sought shortly before the procedure will be carried out, this will naturally be done by the health care professional responsible.

Teamwork is recognised as a crucial part of the way the NHS operates. Where written consent is being sought it may be appropriate for other members of the clinical team, who may not be competent or scheduled to do the procedure itself, to participate in the process of seeking consent, as long as they are in a position to provide all appropriate advice to the patient and answer any questions they may have about the procedure.

In general, specialist trainees and above and nurse practitioners are deemed capable of performing procedures and therefore competent to seek patients' consent for those procedures. Junior doctors (more junior than specialist trainees) will not be considered competent to seek patient consent for procedures they cannot perform, unless they have first completed a formal delegated consent training package relevant to the specialty they are working in and have been formally assessed as competent to take consent for that particular procedure.

b) Delegated consent for elective procedures

The healthcare professional providing the treatment or investigation is responsible for ensuring that the patient has given valid consent before treatment begins, although the consultant responsible for the patient's care will remain ultimately responsible for the quality of medical care provided.

GMC guidance states that the task of seeking consent may be delegated to another person, as long as they are suitably trained and qualified and competent to do so, to work within their own competence and do not agree to perform tasks which exceed that competence.

Totally follows the principle that written consent for elective procedures will be sought by staff who are capable of performing the procedure. This generally means that it will be a consultant, specialist trainee or specialist nurse/nurse practitioner who will be seeking consent for elective procedures.

It is recognised, however, that in some specialties it may be appropriate for consent to be delegated to a staff member who is not capable of performing the procedure. If this is judged appropriate by senior medical staff, they are responsible for assessing the competency of the staff to whom they wish to delegate consent and it is they who must apply the following conditions:

- The individual providing the information must be conversant with the procedure and must understand the materiality of the risks involved.
- She/he must have been trained in obtaining consent for the specific procedure and have been formally assessed and signed off as competent to take consent for the procedure.
- She/he must have satisfactory communication skills.
- The process must be subject to an annual audit.
- Adequate literature describing the procedure, its benefits and risks, and any alternatives, must always be given to the patient.
- The patient must have proper access to the delegating clinician, in order to discuss any concerns that cannot be answered by the delegated individual.

If a clinician takes consent for a procedure, they are not competent to perform and have not been formally assessed as being competent to take delegated consent for, an incident form must be completed and the incident investigated by the Medical Director.

Health care professionals who feel pressurised or asked inappropriately to seek consent should contact the Medical Director.

c) Interventional Radiology

Some procedures are primarily technical investigations carried out at the request of the referring clinician (e.g., invasive radiological procedures). In these cases, the referring clinician (or an appropriately trained and delegated individual) must explain to the patient how the procedure fits into the plan of care and what alternatives exist. The referring clinician (or an appropriately trained and delegated individual) must also be able to explain, in broad terms, the material risks associated with the procedure for which they are being referred. These should be identified in any patient information leaflet and given to the patient.

On the day of the procedure, the practitioner performing the procedure must ensure that the patient is validly consenting to the procedure being undertaken, has received an explanation of the material risks, and be in a position to answer any further questions the patient may have about the procedure before undertaking it. The practitioner will then be in a position to confirm that valid consent has been given.

4. Guidance on consent

The Department of Health has issued a number of guidance documents on consent and the General Medical Council (GMC) has also published a guidance document on consent. These may be consulted for advice on the current law and best practice requirements in seeking consent. Healthcare professionals must also be aware of any guidance on consent issued by their own regulatory bodies. Copies are available from:

- The internet at www.doh.gov.uk/consent
- The internet at www.gmc-uk.org

'12 key points on consent: the law in England' has been distributed widely to healthcare professionals working in England and is attached as **Appendix 2.** This one-page document summarises those aspects of the law on consent that arise on a daily basis. Copies are available from www.doh.gov.uk/consent.

Human Tissue Act 2004, HTA Code of Practice on Consent

Mental Capacity Act, 2005 and associated Code of Practice

5. Documenting consent

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 a healthcare professional has 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 prudent to do so. For patients who lack capacity to consent to care and treatment, the principles of the Mental Capacity Act must be adhered to.

For significant procedures it is essential that health care professionals document clearly both a patient's agreement to the intervention and the discussions that 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), or through documenting in the patient's notes that they have given oral consent.

a) The need for written consent

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.

It is good practice to seek written consent, particularly 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 care professionals would describe as 'side-effects' or 'complications')
- The procedure involves general/regional anaesthesia or sedation
- Providing clinical care is not the primary purpose of the procedure
- There may be significant consequences for the patient's employment, social or personal life from the procedure or its attendant significant risks
- The treatment is part of a project or programme of research (which must have been approved by Totally)

Completed consent forms should be kept in the patient's notes (pink copy). The white copy should be given to the patient. If the patient refuses the white copy, this should be circled on the consent form.

If any change is proposed to a consent described on a 'consent to treatment' form, the health professional agreeing the change with the patient must ensure that:

- a new consent form is completed
- the previous consent form is made void, but retained within the health record; and
- any associated waiting list data (manual and computer-held, including operating lists) is changed.

If a change is made to a verbal consent and there is no written consent form, the change must be documented clearly in the health record so that there can be no doubt about the status of consent.

If the patient has capacity, but has problems reading or writing, the principles of informed consent still apply. Staff should attempt to obtain a unique identifying mark or

verbal consent from the patient and document this on the consent form. It would be good practice for the mark to be witnessed by a person other than the healthcare professional seeking consent and for this to be recorded in the patient's notes.

6. Duration of consent

When a patient gives valid consent to an intervention, that consent remains valid for an indefinite duration unless the patient withdraws it. However, if new information becomes available regarding the proposed intervention/procedure (for example new evidence of risks or new treatment options) between the time when consent was sought and when the intervention/procedure is undertaken, GMC guidance states that a doctor or member of the health care team should inform the patient and reconfirm their consent. Similarly, if the patient's condition has changed significantly in the intervening time, it may be necessary to seek consent again, on the basis that the likely benefits and/or risks of the intervention/procedure may also have changed.

7. Seeking consent for anaesthesia

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

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 to make a genuine decision about whether or not to undergo anaesthesia. Patients should therefore receive a general leaflet about anaesthesia from the responsible healthcare professional at their outpatient or pre-admission clinic. The anaesthetist should ensure that the discussion with the patient 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.

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

8. Emergencies

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.

9. 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 and comprehensive information about their condition, about possible treatments/investigations, and about their risks and benefits (including the risks/benefits of doing nothing) and comparative risks with other procedures. 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. Refer to **Appendix 4** for more information on the patient's perspective.

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

Language interpreting and translation services provided by 'Language Empire' can either be via face-to-face interpreters or by a telephone interpreting service.

Totally is committed to ensuring that patients or people with parental responsibility who are deaf or hard of hearing receive the information they need and are able to communicate appropriately with health care staff.

Provision must also be made for blind and partially sighted patients to communicate appropriately in order to obtain informed consent. The consent form should be read to the patient in full and the contents of the form talked through with the patient and the patient asked to confirm their understanding of what is being asked of them. The patient should be given the opportunity to request clarification and ask any questions. Documentation of all communication between the healthcare professional and the patient must be entered into the medical notes.

For partially sighted patients a large print consent form should be used and consideration given to the use of a tape-recorded version of the form with special consideration given to risks and benefits. This will enable the blind or partially sighted person to review the information given to them at their leisure.

As with all consent to examination and treatment, the consenting healthcare professional must satisfy themselves that the patient fully understands the proposed treatment and the potential outcomes.

Totally is committed to ensuring that patients who have a learning disability receive the information they need and are able to communicate appropriately with health care staff.

An easy read version of the patient consent information can be accessed at www.easyhealth.org.uk/fileaccess.aspx?id=1096 entitled 'Questions to Ask.'

The team are also a resource to support staff in planning the admission and discharge of patients with a learning disability.

Access to more detailed or specialist information

Patients may sometimes request more detailed information about their condition or about a proposed treatment than that provided in general leaflets or have a specific requirement. In such cases, information is available from the following sources:

- The National Electronic Library for Health – www.nelh.nhs.uk
- NHS Direct Online – www.nhsdirect.nhs.uk

10. Access to healthcare professionals between formal appointments

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

In Totally the consenting health care professional must insert the name and telephone number of the person the patient may contact in the space provided on the relevant consent form (the patient should be given the white copy).

Open Access Clinics

Where patients access clinics directly, it should not be assumed that their presence at the clinic implies consent to particular treatment.

Health care professionals should ensure that patients have the information they need before proceeding with an investigation or treatment. It is the responsibility of the health care professional treating the patient to ensure that the relevant information is given to the patient, and that they have the opportunity to ask questions before proceeding or refusing to undergo either investigation or treatment.

11. Refusal of treatment

If the process of seeking consent is to be a meaningful one (and the consent valid), refusal must be one of the patient's options. A competent adult patient is entitled to refuse treatment, except in circumstances governed by the Mental Health Act 1983. The position of children is more complex: see the Department of Health's 'Seeking consent; working with children' for more detail.

Where children or parents refuse recommended treatment health care professionals should seek specialist medico-legal advice via the Company Secretary. The following paragraphs apply primarily to adults.

If, after discussion of possible treatment options, a patient refuses all treatment, the consultant with overall responsibility must be informed and the facts should be clearly documented in the patient's notes. If the patient has signed a consent form, but subsequently changes their mind, the health care professional should note this on the form, and request that the patient countersigns this.

Where a patient has refused a particular intervention the health care professional must ensure that they continue to provide any other appropriate care to which the patient has consented, and 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, patients should be advised accordingly.

If a patient consents to a particular procedure but refuses certain aspects of the intervention, the health care professional must explain to the patient the possible consequences of their partial refusal. If the health care professional considers that the procedure cannot be safely carried out under the patient's stipulations, they are not obliged to perform it. The health care professional must, however, continue to provide any other appropriate care.

Where another health care professional believes that the treatment can be safely carried out under the conditions specified by the patient, the original health care professional must, on request, transfer the patient's care to that health care professional.

12. Consent for the use of human tissue

The legal position regarding the use of human tissue (including blood samples and other bodily fluids provided for testing) is described by the Human Tissue Act (HTA) 2004. Guidance has been published by the Human Tissue Authority (2006) http://www.hta.gov.uk. Such tissue can be very valuable for audit, quality assurance of diagnostic tests, education, and research. Such use may lead to developments in medical knowledge and hence improvements in healthcare for all.

The HTA recognises that tissue may be taken in a variety of circumstances. For example:

- In the course of diagnostic procedures, e.g. taking blood or urine samples, tissue biopsy, cervical screening, etc.
- In the course of a treatment or procedure, e.g. removing tissue (organs, tumours, etc) during surgery.
- When removing tissue specifically for the purpose of research.

a) When consent is needed

Consent from the living is needed for use (and storage) of tissue for:

- Obtaining scientific or medical information that is intended to be of principal relevance to another person, now or in future (i.e. where the purpose is storage or use in relation to another person, rather than where it might, incidentally, be of future relevance to another person)
- Research in relation to disorders or functioning of the human body
- Public display
- Transplantation

b) Consent for research linked to the medical record

Patients may give permission for tissue taken from them during surgery or other procedure to be used for ethically approved research that is linked to their medical record / clinical data. This can be done in three ways:

Patients may give permission for tissue taken from them during surgery or other procedure to be used for ethically approved research that is linked to their medical record / clinical data. This can be done in three ways:

- During the normal consent process for the procedure, using the standard consent to treatment form. There is a section relating to research on the consent form and information is provided on the back. This method of consent is suitable for research that is conducted in Totally, the NHS.
- Via specially trained professionals associated with the hospital Biobank. Consent must be taken by this route where tissue is to be made available to users outside the NHS, such as other universities and pharmaceutical companies,
- Via a research project consent (which has appropriate ethical approval)

d) Permissible uses of tissue without consent

Once tissue has been taken from living patients, for whatever purpose, it can be stored and used without consent for the following purposes:

- Clinical Audit
- Education or training relating to human health (including training for research into disorders, or the functioning of the human body)
- Performance assessment
- Public health monitoring
- Quality assurance
- Research only where (1) the research has appropriate ethical and R&D approval and (2) the tissue is anonymised so that the researcher does not have information which can identify the person from whose body the material has come (and is not likely to come into possession of such information)

e) Anonymity in research on tissues

In general, obtaining consent is preferable to developing systems for keeping samples

anonymised (unlinked). Consented use is best practice and has the added benefit of facilitating the process of obtaining ethical approval.

Anonymisation does not require that samples are permanently and irrevocably unlinked from the donor (a link can be made through a third party where necessary).

Persons holding the tissue can themselves carry out the research on anonymised samples.

If members of the clinical team take part in the research, links may be retained to the relevant clinical or patient records, but they must not contain information giving direct patient identification (i.e., there should be an intermediate identification to preserve anonymity).

13. Research and innovative treatment

The same legal principles apply when seeking consent from a person for research purposes and when seeking consent for investigation and treatment. GMC guidance advises that patients 'should be told how the proposed treatment differs from the usual methods, why it is being offered, and if there are any additional risks or uncertainties.'

Clinical trials are covered by the 'Medicines for Human Use (Clinical Trial) Regulations 2004.5

If the treatment being offered is of experimental nature, but not actually part of a research trial, this fact must be clearly explained to a person with capacity before their consent is sought, along with information about standard alternatives. It is good practice to give a person information about the evidence to date of the effectiveness of the new treatment, both at national/international levels and in the practitioner's own experience, including information about known possible side effects.

Where the person is an adult who lacks capacity, or a child, then the experimental treatment cannot be given, unless it is in their best interests. Where there is no alternative treatment available and the disease is progressive and fatal, it will be reasonable to consider experimental treatment with unknown benefits and risks but without significant risks of increased suffering to the patient, and where there is some chance of benefit to the patient.

14. Consent requirements concerning gametes

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

Outside specialist infertility practice, these requirements may be relevant to health care professionals whose patients are about to undergo treatment that might render them sterile (such as chemotherapy or radiotherapy), where a patient may wish to have gametes, or ovarian or testicular tissue, stored prior to the procedure.

Health care professionals may also receive requests to remove gametes from a person who is unable to give consent.

15. Consent requirements for living donation

The Human Tissue Authority is responsible for the regulation, through a system of approvals, of the donation from living people of solid organs, bone marrow and peripheral blood stem cells for transplantation into others. Information on the legal requirements and how to proceed is available from the Authority – www.hta.gov.uk.

16. Consent for 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.

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 consent of the patient or a person with parental responsibility for the patient. The one exception to this principle is set out in paragraph 3 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. 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 you 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. 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. 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.

Diversity, Equality and Inclusion

Totally recognises that some sections of society experience prejudice and discrimination. Discrimination can come in one of the following forms:

- **Direct discrimination** - is when someone is treated unfairly because of a protected characteristic
- **Indirect discrimination** - putting rules or arrangements in place that apply to everyone, but that put someone with a protected characteristic at an unfair disadvantage
- **Discrimination by association** - this is when a person is treated less favourably because they are linked or associated with a protected characteristic
- **Discrimination by perception** – this happens when a person is discriminated against because they are thought to have a particular protected characteristic when in fact they do not
- **Harassment** - unwanted behaviour linked to a protected characteristic that violates someone's dignity or creates an offensive environment for them
- **Victimisation** - treating someone unfairly because they have complained about discrimination or harassment

The Equality Act 2010 specifically recognises the 'protected characteristics' of age, disability, gender reassignment, race, religion or belief, sex, sexual orientation. The Act also requires regard to socio- economic factors, pregnancy, maternity, marriage, and civil partnership:

Totally is committed to equality of opportunity and anti – discriminatory practice in the provision of services. Totally believes that all people have the right to be treated with dignity and respect and is committed to the elimination of unfair and unlawful discriminatory practices

Totally will provide frameworks that follow the principles of the Diversity, Equality, and Inclusion Policy and will be consistent and fair for all

This falls in line with the company values of Demonstrating Accountability, Being Respectful, Acting with Courage and Delivering Excellence.

Governance

Any consent irregularities should be reported as an Incident on Datix which will be discussed at Clinical Governance Committee Meetings and any learning from such events will be shared with staff through the Clinical Governance framework of meetings.

Reference

Relevant Legislation & National Guidance:

- www.doh.gov.uk/consent
- GMC guideline – Consent: patients and doctors making decisions together (2008)

http://www.gmc-uk.org/guidance/ethical_guidance/consent_guidance/Consent_guidance.pdf

- DH Reference guide to consent for examination or treatment , Second Edition [2009]

http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/documents/digitalasset/dh_103653.pdf

- Consent – what you have a right to expect – DH booklet for patients with versions for adults, children/young people, people with learning disabilities, parents and relatives/carers [2001]

http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@en/documents/digitalasset/dh_4117353.pdf ,

http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@en/documents/ digitalasset/dh_4066989.pdf ,
http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@en/documents/digitalasset/dh_4066993.pdf

- DH Good Practice in consent implementation guide [2001]

http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@en/documents/digitalasset/ dh_4019061.pdf

- DH Seeking consent: working with children [2001]

http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@en/documents/digitalasset/ dh_4067204.pdf

- Human Tissue Act [2004] Human Tissue Act 2004 (c. 30) HTA Code of Practice on Consent 2006 - Code 1 -Consent
- Confidentiality: NHS Code of Practice [2003]
- Mental Capacity Act [2005] and Code of Practice www.dh.gov.uk
- PH Safeguarding Adults Policy and Safeguarding Children
- Human Tissues Management for Scheduled Purposes Under the Human Tissues Act (2004)

Appendices

Appendix 1

Brief Guide to Consent for Children and Young People

Introduction

This brief guide has been written to help inform and support staff making decision when providing health care to children, young people and their families.

Rights and Interests of Children

General Medical Council (UK) guidance:-

"You should involve children and young people as much as possible in discussions about their case, even if they are not able to make decisions."

"A young person's ability to make decisions depends more on their ability to understand and weigh up options, than on their age."

There are three main legal areas that govern the legal rights of children and protect their interests. These include:

- The Children Act 1989
- Family Reform Act 1969
- Common Law: Gillick vs.West Norfolk and Wisbech Area Health Authority 1996 (Scotland has different Acts)

The Children Act 1989

This Act outlines that the child's welfare is of utmost importance and their views must be respected in the appropriate circumstances. It is a list of general principles that one should keep in mind when dealing with cases involving children so as to maximally promote and protect their general welfare and to guide actions that are in their best interest.

Although aimed at court decisions, is useful for medical practice, in particular:-

- "A court shall regard in particular to the ascertainable wishes and feelings of the child concerned"
- "His physical, emotional and educational needs."
- "The likely effect on him of any change in his circumstances"
- "Any harm which he has suffered or is at risk of suffering"
- "How capable parents and other people are in meeting the needs of the children"

- "The age, sex and background, and any characteristics which the court considers relevant."

It also outlines exactly who has parental responsibility or guardianship.

The Act allows anyone with parental responsibility to act alone (the consent of one parent is necessary)

Parental Responsibility (entitles a person to give consent to medical treatment (including investigations) for their child:

A mother automatically has parental responsibility for her child from birth.

A father usually has parental responsibility if he is:

- married to the child's mother
- listed on the birth certificate (after a certain date, depending on which part of the UK the child was born in)

Parental responsibility can be applied for if it is not an automatic right.

Births registered in England and Wales

- **If the parents of a child are married** when the child is born, or if they have jointly adopted a child, both have parental responsibility. They both keep parental responsibility if they later divorce.

- **Unmarried parents**

  An unmarried father can only get legal responsibility for his child in one of three ways:

  1. getting a parental responsibility agreement with the mother
  2. jointly registering the birth of the child with the mother (from 1 December 2003)
  3. getting a parental responsibility order from a court

Births registered in Scotland

- A father has parental responsibility if he is married to the mother when the child is conceived, or marries her at any point afterwards.
- An unmarried father has parental responsibility if he is named on the child's birth certificate (from 4 May 2006).

Births registered in Northern Ireland

- A father has parental responsibility if he is married to the mother at the time of the child's birth.
- If a father marries the mother after the child's birth, he has parental responsibility if he lives in Northern Ireland at the time of the marriage.
- An unmarried father has parental responsibility if he is named, or becomes named, on the child's birth certificate (from 15 April 2002).

Births registered outside the UK

- If a child is born overseas and comes to live in the UK, parental responsibility depends on the UK country they are now living in.

Same-sex parents

Civil partners (including civil marriages)

- Same-sex partners who were civil partners at the time of the treatment will both have parental responsibility.

Non-civil partners

- For same-sex partners who are not civil partners, the second parent can get parental responsibility by either:
  - applying for parental responsibility if a parental agreement was made
  - becoming a civil partner of the other parent and making a parental responsibility agreement or jointly registering the birth

The situation if parents are absent

- There is no requirement that a parent be physically present when consent/treatment is given. If they can be contacted, whether by phone or email, and given the information relevant to the treatment, their verbal consent will be valid
- The Children Act s2(9) provides that a person who holds parental responsibility may not "surrender or transfer any part of that responsibility to another, **but may arrange for some or all of it to be met by one or more persons acting on their behalf"**
- The Children Act s3(5) provides that a person who does not have parental responsibility but "has care of the child" may "do what is reasonable in all the circumstances of the case for the purpose of safeguarding or promoting the child's welfare"

Common Law: Gillick v West Norfolk and Wisbech Area Health Authority 1984-5

"Gillick Competence" - any child who is under the age of 16 can consent if he or she "reaches a sufficient understanding and intelligence to be capable of making up his own mind on the matter requiring decision".

This however, does not mean they have a right to refuse treatment.

Also, what is deemed 'sufficient' for understanding and intelligence?

"Gillick And Fraser are not interchangeable"

Gillick competence refers to the assessment that doctors could make in regards to whether a child under 16 has the capacity to consent to treatment without parental or guardian consent. Fraser guidelines is in reference to Lord Fraser's involvement with the Gillick case. He commented on the responsibility of doctors to ensure adequate capacity of children specifically on receiving contraceptive prescription and advice. It makes no comment on the capacity of children for any other treatments or procedure.

Family Law Reform Act 1969

Those who are 16 years old or above have the same legal ability to consent to any medical, surgical or dental treatment as anyone above 18, without the consent from his/her parent or guardian.

This does NOT mean that they have a right to refuse treatment.

Right to Refuse Treatment

- Those who are under 18 years old who has capacity and refuses therapeutic treatment, as long as there is one consenting parent or guardian (even if the other refuses), the medical staff can proceed.
- This is because it is done with the best interest of the child in mind.
- However if the intervention is non-therapeutic (i.e. male circumcision on religious grounds) and both parents disagree, then a court ruling should be sought.
- If the treatment/investigation is non-urgent but still in the best interests of the child the clinician can request a "specific issue order" under the Children's Act 1989.
- Once a minor is made ward of the court, then no major treatment can be given without permission of the court.

Mental Capacity Act 2005

The Mental Capacity Act (MCA) is designed to protect and empower individuals who may lack the mental capacity to make their own decisions about their care and treatment. It is a law that applies to **individuals aged 16 and over**.

Please refer to the Mental Capacity Act for further guidance.

Family Courts or Family Division of High Court

The various types of Family Court handle:

- parental disputes over the upbringing of children
- local authority intervention to protect children
- decrees relating to divorce
- financial support for children after divorce or relationship breakdown
- some aspects of domestic violence
- adoption

Family matters are dealt with in the Family Division of the High Court, by district judges in County Courts and in Family Proceedings Courts, which are specialist Magistrates' Courts.

Magistrates undergo specialist training before they sit in Family Proceedings Courts, where procedures are very different from the criminal courts.

The Court of Protection

The Court of Protection was established under the terms of the Mental Capacity Act 2005, which came into force on 1 October 2007.

It is a specialist court which makes specific decisions or appoints other people known as deputies to make decisions on behalf of people who lack the capacity to do so for themselves.

The Court of Protection can:

- decide whether a person 'has capacity' (is able) to make a particular decision for themselves
- make declarations, decisions or orders on financial or welfare matters affecting people who lack capacity to make these decisions
- appoint a deputy to make ongoing decisions for people lacking capacity to make those decisions
- decide whether a Lasting Power of Attorney (LPA) or Enduring Power of Attorney (EPA) is valid
- remove deputies or attorneys who fail to carry out their duties
- hear cases concerning objections to register an LPA or EPA

Cases are heard by circuit, district and High Court judges, at the central registry in Archway and at courts throughout England and Wales. Hearings are normally private, but in certain cases the media can be authorised to attend.

Confidentiality

Provided by latest GMC guidelines on confidentiality:

- Information can be shared with others providing care, but if the patient refuses consent to share their wishes should be upheld unless the patient is at risk of death or serious harm

- "You must not disclose personal information to a third party such as a solicitor, police officer or officer of a court without the patient's express consent", except in these circumstances: -
- "Where a disclosure may assist in the prevention, detection, or prosecution of a serious crime,
- The patient or others is at risk of death or serious harm especially crimes against the person, such as abuse of children."

Whether to breach confidentiality or not is the judgement of the health care professional who must decide whether without disclosure, the child is at risk of serious harm.

Generally speaking, disclosure is seen as acceptable if a child is under 13, or the partner involved is 18 or above. A grey area would be those involved who are between 14 and 17 and are Gillick competent, and refuse to disclose to their parents or for the doctor to disclose this information. In these cases, one should assess whether serious harm is involved, and whether a breach in confidentiality will affect the doctor-patient relationship (see below).

Young women under 18 years of age attending for termination of pregnancy

Young women aged under 18 attending for termination of pregnancy may wish this to be kept confidential from their parents/carers, therefore it may be that no one with parental responsibility is aware of their planned treatment.

"Concern about confidentiality is the biggest deterrent to young people asking for sexual health advice" [Paragraph 64 GMC guidance on Good Medical Practice for 0-18 years], so it is important that young people are assured of confidentiality. However, breach of medical confidentiality may be justified in some circumstances, where there is a serious risk to the health , safety or welfare of the young person and the likely harm from non-disclosure outweighs both the possible harm to the young woman and to the trust between her and the clinician. There should be a high threshold for justifying any breach of confidentiality to ensure that healthcare professionals are seen to maintain a confidential health service.

The clinician responsible for listing the young person for the procedure will assess her capacity to consent to treatment. If the young person is not deemed competent to consent to treatment, the healthcare professional will need to make a decision in the best interests of the young person about potentially breaching confidentiality and sharing the information.

Where the young woman is deemed to have capacity to consent to treatment, but is under 16 years of age, the clinicians should encourage her to inform her parents or carers, and offer support for her to do so.

The clinicians will ensure that the young person has someone to collect them following the procedure - to transport her home and ensure that there is a responsible and physically fit person to look after them for the first 24 hours post according to the PH discharge and transfer policy CLCGPO36.

Where a young person who has capacity to consent does not agree to inform her parents or carers despite the clinician's attempts to encourage her to do so, this must be respected, but discussion should take place to encourage her to consider how she will explain her absence from home and arrangements made for her to be escorted home by a responsible person who will also be able to provide care for the first 24 hours post procedure. The young person should be encouraged to inform another adult whom she trusts and for the records. The clinical team will need to decide in which circumstances parents should be contacted, information to be shared with her GP.

Assurance should be given that confidentiality will not be breached unless there are significant unforeseen complications to treatment. The young person should be asked to share the contact details of her parents /carers and agree for them to be used ONLY in these circumstances. This should be clearly documented in based on the best interests of the young person.

If the young person still does not agree to share information, this should be clearly documented in the records. However, there may be extreme circumstances where the clinical team feel it is still appropriate to breach confidentiality in the best interests of the young person, and advice should be sought about this from the safeguarding team. In any circumstance where confidentiality is breached the clinician should fully document their reasons for disclosing the information without consent and the steps taken to try to obtain consent.

Clinicians should tell the young person what they propose to disclose and why unless there is a good reason not to (and should document this).

References:

- Mental Capacity Act Code of Practice 2005
- General Medical Council: Consent, Good Medical Practice
- www.gov.uk

Diagram to guide application of law to consent

Age in Years	Children's Act 1989	Gillick Competence 1996	Family Law Reform Act 1969	Mental Capacity Act (MCA) 2005	Mental Capacity Act and Safeguarding	Mental Health Act 1983	Family Courts or Family Division of High Court	Court of Protection
0 11	Someone with 'Parental Responsibility' required to consent. In emergency situations the consultant may consent in the child or young person's best interests.	Approx age…. Young people can consent if 'Gillick Competent' This is generally in addition to consent from PR but may be instead of.		Only applies to decisions about property and financial affairs (from the Court of Protection)	MCA can apply if someone mistreats or neglects a child who lacks capacity	Mental Health Act may apply if neither Children's Act or MCA appropriate	Generally hear cases involving CYP where there are disagreements between parties (YP, person with PR and/or care providers). Decisions only apply until YP 18 years old.	Hear cases where decisions would apply beyond 18 years old e.g. where a 17 year old is to live who will not regain capacity.
12 15								
16 17			Presumes that YP have capacity to consent except for • Organ Donation • Non therapeutic procedures • Research	Applies if someone lacks capacity to make a decision. Note exceptions cannot: • make Lasting Powers of Attorney • make advanced decisions to refuse treatment • make a will				
	There are currently no specific rules for deciding when to use either the Children Act 1989 or the Mental Capacity Act 2005 or when to apply to the High Court. Seek advice if unsure.							
18+								
Evidence required	Consent	Consent	Consent	MCA two stage test of capacity	MCA two stage test of capacity	MHA documentation	Court order	Court order
Confidentiality	Care should be taken not to unlawfully breach a YP right to confidentiality							

Appendix 2

12 key points on consent: the law in England

DH Department of Health

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 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.

Is the patient's consent voluntary?

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. Not 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.

Refusals of treatment

10. Competent adult patients are entitled to refuse treatment, even where 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*. A competent pregnant woman may refuse any treatment, even if this would be detrimental to the fetus.

Adults who are not competent to give consent

11. **No-one** can give consent on behalf of an incompetent adult. 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.
12. If an incompetent patient 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 and at www.doh.gov.uk/consent

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Appendix 3

SEEKING A COURT DECLARATION

1. When there is not a consensus on whether a particular treatment is in an incapacitated adult's best interests and where the consequences of having, or not having, the treatment are potentially serious, a court declaration may be sought.
2. Where there are concerns about a patient's competence (capacity) to consent or refuse treatment and the best interests of the patient is unclear, a court order can be sought.
3. In a life threatening emergency, where capacity is in doubt and consultation with either the person with overall (including parental) responsibility or a court is impossible, or where the person with overall responsibility refuses consent despite such emergency treatment appearing to be in the best interest of the individual, the courts have stated that doubt should be resolved in favour of preservation of life and it will be acceptable to undertake treatment to preserve life or prevent serious damage to health.
4. The Department of Health's Reference Guide to Consent for Examination and Treatment is also a useful source of guidance – www.doh.gov.uk/consent.